

# **EPA Registration File 67690-31**

## **Vol. 1**



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

December 2, 2004

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

MR. STEVE COCKREHAM  
SEPRO CORP  
11550 N. MERIDIAN ST SUITE 600  
CARMEL, IN 46032

Dear Mr. Cockreham:

Subject: Transfer of Pesticide Registrations and Data From Company Number 1812 to  
Company Number 67690

Pursuant to your request in your letter and transfer agreement of August 17, 2004 and subsequent information received November 9, 2004, we have approved the transfer of the following registrations and data from GRIFFIN L.L.C., company number 1812 to SEPRO CORP, company number 67690.

The effective date of these changes is the date of this letter.

<u>Registered Products</u>	<u>Old EPA Reg. No.</u>	<u>New EPA Reg. No.</u>
K-POOL ALGAECIDE	1812-302	67690-23
K-TEA ALGAECIDE	1812-307	67690-24
KOMEEN	1812-312	67690-25
SPIN OUT	1812-346	67690-26
SPIN OUT 300	1812-357	67690-27
SPIN OUT SPRAY	1812-394	67690-28
SPIN OUT 260	1812-396	67690-29
FLURIDONE SC	1812-435	67690-30
FLURIDONE TECHNICAL	1812-436	67690-31
FLURIDONE SRP	1812-447	67690-32

<u>Pending Registered Products</u>	<u>Old EPA File Symbol</u>	<u>New EPA File Symbol</u>
SPIN OUT NURSERY CONTAINERS	1812-ULO	67690-GG



You should indicate the new company designation, new EPA Registration Number and new Establishment Number (if it has changed) on the labeling at the next printing which should occur no later than 18 months after the effective date of this transfer. After 18 months, any product released for shipment must bear the new Registration Number and Establishment Number. If you intend to use the labels which currently appear on the transferor's product after the effective date of the transfer, but within the 18 month grace period, you must maintain complete and accurate records which identify by batch number, lot number, or other suitable description the quantities of such product bearing the transferor's label. Each container or package bearing the transferor's label which is released after the effective date of product registration transfer, must be clearly and accurately marked with the batch number, lot number or other descriptive designation used to identify the product in your records.

Supplemental distribution agreements of registered products do not transfer with the Section 3 registration. It is your responsibility as the registrant to notify any and all supplemental distributors of the transferred product(s) of this transfer agreement. If you wish to enter into supplemental distribution agreements of your product(s) under this new registration, the form "Notice of Supplemental Distribution of a Registered Pesticide Product," EPA Form 8570-5, must be submitted to the Agency for each supplemental distributorship.

You are required to contact your local EPA Regional Office to determine what effect this transfer of pesticide registrations has on the pesticide production establishment registration.

It will not be necessary to submit labeling for review if the only changes are in the company designation and the EPA Registration Number. Other changes in the product and/or labeling may require EPA review and approval prior to initiation. In any correspondence on these products always refer to the U.S. EPA Registration Number listed above.

The transferred registration will have the same status under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, 7 USC 136 et seq., as it had prior to the approval of this transfer.

When registrations are transferred from one company to a second company, all restrictions, data requirements, conditions (suspensions), and deadlines existing on the registrations are transferred with the registrations. The new company is responsible for adhering to or complying with all such restrictions, etc. on the acquired products.

In regard to deadlines, the transferee company is responsible for submitting all required data according to the schedules already established for the acquired products. Failure to do so will result in the issuance of a Notice of Intent to Suspend. Requests from transferee companies for additional time to submit, because they acquired the registration(s) after the 3(c)(2)(B) request was issued will not be granted. If a transferee company has other valid reasons for delays in the testing which were clearly outside of their control, then such requests for time extensions will be considered in accordance with the established procedures. Transfers occurring while a 3(c)(2)(B) request is being issued or during the 90-day response time are subject to the same conditions expressed above.

Registration is in no way to be construed as an endorsement or approval of these products by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with FIFRA.

Furthermore, the transfer of the subject registrations is approved under the condition that the annual maintenance fee obligation has been fully satisfied. The marginal maintenance fee is determined based solely on the total number of active section 3 and section 24(c) registrations held by the transferor. If the annual maintenance fee has not been fully satisfied, the transferee and transferor will be notified to comply within a specified time period or the affected registrations may be canceled.

The Agency acknowledges it has received a request for data transfer dated August 17, 2004 and subsequent information received on November 9, 2004 to transfer data ownership from the transferor to the transferee. The data transfer is effective the date of this letter. After this date SEPRO CORP will be considered the data owner. This action will not automatically reflect on the Data Submitters List. If you want to be added to the Data Submitters List, you must submit a request to:

Document Processing Desk (DSL)  
Office of Pesticide Programs (7504C)  
U.S. Environmental Protection Agency  
Ariel Rios Building  
1200 Pennsylvania Avenue, NW  
Washington, DC 20460

By copy of this letter we are informing the transferor of these changes. If you have any questions about this transfer approval please contact Alexandra Zikely at (703) 305-6603.

Sincerely,



Kate Bouve', Cheif  
Information Services Branch  
Information Resources & Services Div. (7504C)

cc: MS. PRISCILA VANSETTI  
DUPONT CROP PROTECTION/STINE-HASKELL RESEARCH CENTER,  
AGENT FOR  
GRIFFIN L.L.C.  
1090 ELKTON ROAD, PO BOX 30  
NEWARK, DE 19714-0030



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

FEB - 6 2004

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

W.A. Hawkins Ph.D.  
Griffin Corporation  
P.O. Box 1847  
Valdosta, GA 31603-1847

Dear Dr. Hawkins:

Subject: 5-Batch Analysis  
Fluridone Technical  
EPA Registration No. 1812-436  
Your Submission Dated July 14, 2003

The Study "Griffin Technical Fluridone Analysis of Product Ingredients" MRID # 460338-01 is acceptable. For your information enclosed is a copy of the scientific review.

If you have any questions concerning this letter, please contact Mr. James Stone at 703-305-7391.

Sincerely yours,

JS

Joanne I. Miller  
Product Manager (23)  
Herbicide Branch  
Registration Division (7505C)

Enclosure

\*Manufacturing process information may be entitled to confidential treatment\*

**DATE OUT: 01/29/2004**

**SUBJECT: PRODUCT CHEMISTRY REVIEW OF MP ☐ EP ☒**

**DP BARCODE No.:D294233 REG./File Symbol No. :1812-436**

**PRODUCT NAME: FLURIDONE TECHNICAL**

**PC Codes** 112900

**Decision #** 333423

**COMPANY: GRIFFIN L.L.C.**

**FROM:** Indira Gairola, Chemist  
Product Chemistry Team  
Technical Review Branch/RD (7505C)

*SRM 1/29/04*

**TO:** Joanne Miller PM 23  
Herbicide Branch(7505C)

**INTRODUCTION:**

GRIFFIN L.L.C. has submitted Guideline Reference 830.1700 Preliminary Analysis of Fluridone Technical (MRID# 460338-01) for the subject product FLURIDONE TECHNICAL. TRB findings are listed below.

**SUMMARY OF FINDINGS:**

1. The submitted Guideline Reference 830.1700 Preliminary Analysis of Fluridone Technical (MRID# 460338-01) for the subject product FLURIDONE TECHNICAL was for five batch analysis. The study initiated on April 1, 2003 and concluded on July 2, 2003.
2. The study was conducted in accordance with the requirements of U.S. Environmental Protection Agency Good Laboratory Practice 40 CFR § 160, FIFRA.
3. The study was accompanied by Quality Assurance statement 40 CFR § 160.
4. Fluridone was determined by GC with FID detector with automatic sampler system.
5. Comparison of the peaks of the sample with that of a Fluridone analytical standard of known purity was made, using [REDACTED] as an internal standard.
6. Average recovery of the active ingredient Fluridone ranged from 96.5%-98.16%. Mean Average recovery reported was 97.7%.
7. Results and calculations were included along with the submission.

8. Results of Fluridone showed good recovery, and are acceptable .

**CONCLUSIONS:**

TRB has reviewed the aforementioned Data and concludes:

1. Results of Fluridone Technical (MRID# 460338-01) for the subject product FLURIDONE TECHNICAL showed good recovery of Fluridone
2. The data of fulfill the requirement of OPPTS Guideline Reference 830.1700 Preliminary Analysis of FLURIDONE TECHNICAL



**DATA PACKAGE BEAN SHEET**

Date: 07-Oct-2003

Page 1 of 3

**\*\*\* Registration Information \*\*\***

Registration: 1812-436 - FLURIDONE TECHNICAL

Company: 1812 - GRIFFIN L.L.C.

Risk Manager: RM 23 - Joanne - Miller - (703) 305-6224 Room# CM-2 241

Risk Manager Reviewer: James Stone - JSTONE

Sent Date: 21-Jul-2003

Calculated Due Date: 04-Nov-2003

Edited Due Date: \_\_\_\_\_

Type of Registration: Product Registration - Section 3

Action Desc: CONDITIONAL REGISTRATION FOLLOW-UP;DATA REQUIRED;REQUIRES RD REVIEW;

Ingredients: 112900

**\*\*\* Data Package Information \*\*\***Expedite: ☐ Yes ☒ No

Date Sent: 07-Oct-2003

Due Back: \_\_\_\_\_

DP Ingredient: 112900, Fluridone

DP Title: \_\_\_\_\_

CSF Included: ☒ Yes ☐ NoLabel Included: ☒ Yes ☐ No

Parent DP #: \_\_\_\_\_

**Assigned To****Date In****Date Out**

Organization: RD / TRB

Administrative Due Date: 16-Dec-2003

Team Name: Chem

Negotiated Due Date: 2-11-04

Reviewer Name: \_\_\_\_\_

Projected Completion Date: \_\_\_\_\_

Contractor Name: \_\_\_\_\_

**\*\*\* Studies Sent for Review \*\*\***

Printed on Page 2

**\*\*\* Additional Data Package for this Decision \*\*\***

Printed on Page 3

**\*\*\* Data Package Instructions \*\*\***

Please review Five Batch Analysis requested for [REDACTED] alternate source.

\*Product ingredient source information may be entitled to confidential treatment\*



Read instructions on reverse before completing form.

Form Approved, OMB No. 2070-0060, Approval expires 2-28-95



United States  
Environmental Protection Agency  
Washington, DC 20460

☐ Registration  
☐ Amendment  
☒ Other

OPP Identifier Number

### Application for Pesticide - Section I

1. Company/Product Number 1812 -436	2. EPA Product Manager Joanne I. Miller	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Fluridone Technical	PM# 23	
5. Name and Address of Applicant (Include ZIP Code) Griffin L.L.C. P. O. Box 1847 Valdosta, GA 31603-1847 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

### Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated <u>04/09/02</u>	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Submission of 5-batch analysis on product from a new production facility as required by the Agency's letter dated April 9, 2002

### Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
If "Yes" Unit Packaging wgt. No. per container		If "Yes" Package wgt. No. per container			
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled				<input type="checkbox"/> Other _____	

### Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name W. A. Hawkins, Jr., Ph.D.		Title Senior Registration Manager		Telephone No. (Include Area Code) 229-293-4242, Ext. 1104	
2. Signature 				3. Title Senior Registration Manager	
4. Typed Name W. A. Hawkins, Jr., Ph.D.				5. Date July 14, 2003	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment both under applicable law.				6. Date Application Received (Stamped) 	



VIA UPS NEXT DAY AIR

July 14, 2003

Ms. Joanne I. Miller  
Document Processing Desk (AMEND)  
Office of Pesticide Programs (7504C)  
U.S. Environmental Protection Agency  
Room 266A, Crystal Mall 2  
1921 Jefferson Davis Highway  
Arlington, Virginia 22202-4501

Dear Ms. Miller:

**SUBJECT: Fluridone Technical (EPA REG. NO. 1812-436)  
Amended Confidential Statement of Formula  
Alternative Production Facility  
Submission of Required Data**

In April 2002, the Agency approved an alternate Confidential Statement of Formula dated November 6, 2001 for Fluridone Technical (EPA Reg. No. 1812-436). This alternate CSF indicates that the product is produced by [REDACTED]. In support of this amendment, Griffin was required to submit a 5-batch analysis of product made at [REDACTED]. Three separately bound copies of the results of the analysis are enclosed herewith.

<u>Guideline Number</u>	<u>Document Number</u>	<u>Name of Study</u>	
830.1700	P03-001	Griffin Technical Fluridone – Analysis of Product Ingredients	<b>46033801</b>

Should you require any additional information, please contact me at 229-293-4242, Extension 1104.

GRIFFIN L.L.C.

*W. A. Hawkins, Jr.*

W. A. Hawkins, Jr., Ph.D.  
Senior Registration Manager,  
Copper Products, Insecticides and State Affairs

Griffin L.L.C.

P.O. Box 1847 • Valdosta, GA 31603-1847  
2509 Rocky Ford Rd. • Valdosta, GA 31601  
Telephone: (229) 242-8635  
Facsimile: (229) 244-5813

08/08/03

**FLURIDONE TECHNICAL**

g436s03a

For Manufacturing Use Only

## Active Ingredient

Fluridone:

1-methyl-3-phenyl-5-[3-(trifluoromethyl)phenyl]-4(1*H*)-pyridinone. . . . . 99.2%

Inert Ingredients . . . . . 0.8%

Total. . . . . 100.0%

**KEEP OUT OF REACH OF CHILDREN  
WARNING****ACCEPTED****SEP - 5 2003****STATEMENT OF PRACTICAL TREATMENT**

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act,  
as amended, for the pesticide  
registered under minutes.  
EPA Reg. No. 1812-436

**IF IN EYES:** Hold eyelids open and flush with a steady, gentle stream of water. Get medical attention.

**IF ON SKIN:** Wash with plenty of soap and water. Get medical attention if irritation persists.

**IF SWALLOWED:** Call a doctor or get medical attention. Do not induce vomiting or give anything by mouth to an unconscious person. Drink promptly a large quantity of milk, egg whites, gelatin solution, or if these are not available, drink large quantities of water. Avoid alcohol.

**IF INHALED:** Remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth-to-mouth. Get medical attention.

**FIRST AID**

<b>IF IN EYES:</b>	<ul style="list-style-type: none"> <li>• Hold eye open and rinse slowly and gently with water for 15 to 20 minutes.</li> <li>• Remove contact lenses, if present, after the first five minutes, then continue rinsing eye.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
<b>IF ON SKIN OR CLOTHING:</b>	<ul style="list-style-type: none"> <li>• Take off contaminated clothing.</li> <li>• Rinse skin immediately with plenty of water for 15 to 20 minutes.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
<b>IF SWALLOWED:</b>	<ul style="list-style-type: none"> <li>• Call a poison control center or doctor immediately for treatment advice.</li> <li>• Have person sip a glass of water if able to swallow.</li> <li>• Do not induce vomiting unless told to do so by the poison control center or doctor.</li> <li>• Do not give anything by mouth to an unconscious person.</li> </ul>

<b>IF INHALED:</b>	<ul style="list-style-type: none"> <li>• Move person to fresh air.</li> <li>• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible.</li> <li>• Call a poison control center or doctor for further treatment advice.</li> </ul>
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. <b>For medical emergencies involving this product, call toll free 1-888-324-7598.</b>	
<b>NOTE TO PHYSICIAN:</b> Probable mucosal damage may contraindicate the use of gastric lavage.	
See Label for Additional Precautions and Directions for Use.	

Griffin L.L.C.  
Valdosta, GA 31601

EPA Reg. No. 1812-436  
EPA Est. No.

Net Contents \_\_\_\_\_

[END OF FRONT PANEL]



**PRECAUTIONARY STATEMENTS  
HAZARDS TO HUMANS AND DOMESTIC ANIMALS  
WARNING**

Causes substantial but temporary eye injury. Harmful if swallowed, absorbed through skin or inhaled. Do not get in eyes, on skin or on clothing. Avoid breathing dust. Wear goggles, face shield or safety glasses when handling. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

**ENVIRONMENTAL HAZARDS**

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

**DIRECTIONS FOR USE**

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

**STORAGE AND DISPOSAL**

Do not contaminate water, food or feed by storage or disposal.

**PESTICIDE STORAGE:** Store in original container only. In case of leak or spill, sweep up excess material and dispose of as waste.

**PESTICIDE DISPOSAL:** Wastes resulting from use of this product may be used according to label directions or disposed of at an approved waste disposal facility.

**CONTAINER DISPOSAL:** Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into formulation equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused, dispose of in the same manner.

**For Manufacturing Use Only in Formulating EPA Approved Herbicide Products:** This product may be used only in formulation of herbicide products used for aquatic weed control in fresh water ponds, lakes, reservoirs, drainage canals, irrigation canals and rivers.

## WARRANTY STATEMENT

GRIFFIN warrants that this product conforms to the chemical description on the label thereof and is reasonably fit for purposes stated on such label only when used in accordance with directions under normal use conditions. It is impossible to eliminate all risks inherently associated with use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of GRIFFIN. In no case shall GRIFFIN be liable for consequential, special or indirect damages resulting from the use or handling of this product. All such risks shall be assumed by the Buyer. The exclusive remedy of any buyer or user of this product for any and all losses, injuries, or damages resulting from or in any way arising from the use, handling or application of this product, whether in contract, warranty, tort, negligence, strict liability or otherwise, shall not exceed the purchase price paid for this product or at GRIFFIN'S election, the replacement of this product. GRIFFIN MAKES NO WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS STATED ABOVE.

Griffin and Design are a registered trademark of Griffin Corporation.

*[Based on the EPA stamped accepted label (with comments) dated March 15, 2000 and a notification dated May 25, 2000]*



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

August 13, 2003

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

GRIFFIN L.L.C.  
PO Box 1847  
VALDOSTA, GA 31603-1847

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 17-JUL-03. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

Jacket



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

W.A. Hawkins Ph.D.  
Griffin Corporation  
P.O. Box 1847  
Valdosta, GA 31603-1847

SEP - 5 2003

Dear Dr. Hawkins:

Subject: Revised Labeling  
Fluridone Technical  
EPA Registration No. 1812-436 ✓  
Your Submission Dated August 11, 2003

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended is acceptable provided that you submit one (1) copy of your final printed labeling before you release the product for shipment.

A stamped copy of the labeling is enclosed for your records.

If you have any questions concerning this letter, please contact Mr. James Stone at 703-305-7391.

Sincerely yours,

A handwritten signature in blue ink that reads "Joanne I. Miller".

Joanne I. Miller  
Product Manager (23)  
Herbicide Branch  
Registration Division (7505C)

Enclosure



08/08/03

**FLURIDONE TECHNICAL**

g436s03a

For Manufacturing Use Only

## Active Ingredient

## Fluridone:

1-methyl-3-phenyl-5-[3-(trifluoromethyl)phenyl]-4(1*H*)-pyridinone. . . . . 99.2%

Inert Ingredients . . . . . 0.8%

Total. . . . . 100.0%

**KEEP OUT OF REACH OF CHILDREN  
WARNING****ACCEPTED**  
**SEP - 5 2003****STATEMENT OF PRACTICAL TREATMENT**Under the Federal Insecticide,  
Fungicide, and Rodenticide Act,  
as amended, for the pesticide  
registration minutes.  
EPA Reg. No. 1812-436**IF IN EYES:** Hold eyelids open and flush with a steady, gentle stream of water for 15 to 20 minutes. Get medical attention.**IF ON SKIN:** Wash with plenty of soap and water. Get medical attention if irritation persists.**IF SWALLOWED:** Call a doctor or get medical attention. Do not induce vomiting or give anything by mouth to an unconscious person. Drink promptly a large quantity of milk, egg whites, gelatin solution, or if these are not available, drink large quantities of water. Avoid alcohol.**IF INHALED:** Remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth-to-mouth. Get medical attention.**FIRST AID**

<b>IF IN EYES:</b>	<ul style="list-style-type: none"> <li>• Hold eye open and rinse slowly and gently with water for 15 to 20 minutes.</li> <li>• Remove contact lenses, if present, after the first five minutes, then continue rinsing eye.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
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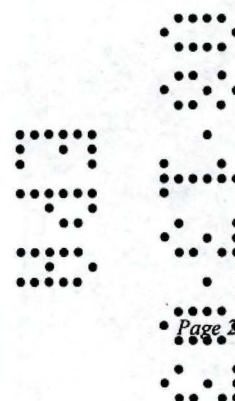
<b>IF INHALED:</b>	<ul style="list-style-type: none"> <li>• Move person to fresh air.</li> <li>• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible.</li> <li>• Call a poison control center or doctor for further treatment advice.</li> </ul>
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. <b>For medical emergencies involving this product, call toll free 1-888-324-7598.</b>	
<b>NOTE TO PHYSICIAN:</b> Probable mucosal damage may contraindicate the use of gastric lavage.	
See Label for Additional Precautions and Directions for Use.	

Griffin L.L.C.  
Valdosta, GA 31601

EPA Reg. No. 1812-436  
EPA Est. No.

Net Contents \_\_\_\_\_

[END OF FRONT PANEL]



**PRECAUTIONARY STATEMENTS  
HAZARDS TO HUMANS AND DOMESTIC ANIMALS  
WARNING**

Causes substantial but temporary eye injury. Harmful if swallowed, absorbed through skin or inhaled. Do not get in eyes, on skin or on clothing. Avoid breathing dust. Wear goggles, face shield or safety glasses when handling. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

**ENVIRONMENTAL HAZARDS**

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

**DIRECTIONS FOR USE**

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

**STORAGE AND DISPOSAL**

Do not contaminate water, food or feed by storage or disposal.

**PESTICIDE STORAGE:** Store in original container only. In case of leak or spill, sweep up excess material and dispose of as waste.

**PESTICIDE DISPOSAL:** Wastes resulting from use of this product may be used according to label directions or disposed of at an approved waste disposal facility.

**CONTAINER DISPOSAL:** Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into formulation equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused, dispose of in the same manner.

**For Manufacturing Use Only in Formulating EPA Approved Herbicide Products:** This product may be used only in formulation of herbicide products used for aquatic weed control in fresh water ponds, lakes, reservoirs, drainage canals, irrigation canals and rivers.

## WARRANTY STATEMENT

GRIFFIN warrants that this product conforms to the chemical description on the label thereof and is reasonably fit for purposes stated on such label only when used in accordance with directions under normal use conditions. It is impossible to eliminate all risks inherently associated with use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of GRIFFIN. In no case shall GRIFFIN be liable for consequential, special or indirect damages resulting from the use or handling of this product. All such risks shall be assumed by the Buyer. The exclusive remedy of any buyer or user of this product for any and all losses, injuries, or damages resulting from or in any way arising from the use, handling or application of this product, whether in contract, warranty, tort, negligence, strict liability or otherwise, shall not exceed the purchase price paid for this product or at GRIFFIN'S election, the replacement of this product. GRIFFIN MAKES NO WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS STATED ABOVE.

Griffin and Design are a registered trademark of Griffin Corporation.

*[Based on the EPA stamped accepted label (with comments) dated March 15, 2000 and a notification dated May 25, 2000]*



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

August 14, 2003

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

W.A. HAWKINS, JR.  
GRIFFIN L.L.C.  
PO Box 1847  
VALDOSTA, GA 31603-1847

PRODUCT NAME: FLURIDONE TECHNICAL  
COMPANY NAME: GRIFFIN L.L.C.  
EPA FILE SYMBOL: 1812-436  
EPA RECEIPT DATE: 08/13/03

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Registration Division, Risk Management Team 23, at (703) 305-6224.

Sincerely,

A handwritten signature in blue ink, appearing to read "J. W. White".

Front End Processing Staff  
Information Services Branch  
Information Resources and Services Division





VIA UPS NEXT DAY AIR

August 11, 2003

Ms. Joanne I. Miller  
Document Processing Desk (AMEND)  
Office of Pesticide Programs (7504C)  
U.S. Environmental Protection Agency  
Room 266A, Crystal Mall 2  
1921 Jefferson Davis Highway  
Arlington, Virginia 22202-4501

Dear Ms. Miller:

**SUBJECT: FLURIDONE TECHNICAL (EPA REG. NO. 1812-436)  
PR NOTICE 2001-1 LABEL AMENDMENT**

Enclosed are five copies of proposed amended labeling for Fluridone Technical (EPA Reg. No. 1812-436). The proposed changes include updating of the First Aid statements as required by PR Notice 2001-1 and a minor change in the section on Storage and Disposal. Proposed deletions are indicated by ~~strikeout~~ and proposed additional text is **highlighted**.

Should you require any additional information, please contact me at 229-293-4242, Extension 1104.

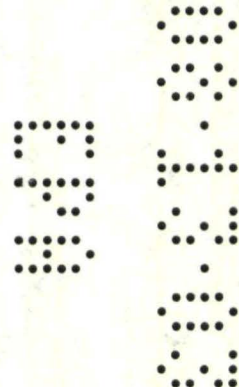
Sincerely,

GRIFFIN L.L.C.

W. A. Hawkins, Jr., Ph.D.  
Senior Registration Manager

Griffin L.L.C.

P.O. Box 1847 • Valdosta, GA 31603-1847  
2509 Rocky Ford Rd. • Valdosta, GA 31601  
Telephone: (229) 242-8635  
Facsimile: (229) 244-5813







Read instructions on reverse before completing form.

Form Approved, OMB No. 2070-0060, Approval expires 2-28-95



United States  
Environmental Protection Agency  
Washington, DC 20460

☐ Registration  
☒ Amendment  
☐ Other

OPP Identifier Number

### Application for Pesticide - Section I

1. Company/Product Number 1812 -436	2. EPA Product Manager Joanne Miller	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Fluridone Technical	PM# 23	
5. Name and Address of Applicant (Include ZIP Code) Griffin L.L.C. P. O. Box 1847 Valdosta, GA 31603-1847 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

### Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

**Explanation:** Use additional page(s) if necessary. (For section I and Section II.)

Label amendment to update First Aid statements to comply with PR Notice 2001-1

### Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Metal Plastic Glass Paper Other (Specify) _____		
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

### Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name W. A. Hawkins, Jr., Ph.D.		Title Senior Registration Manager		Telephone No. (include Area Code) 229-293-4242 Ext. 1104	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received (Stamped)
2. Signature 		3. Title Senior Registration Manager			
4. Typed Name W. A. Hawkins, Jr., Ph.D.		5. Date August 11, 2003			

## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

\*Product ingredient source information may be entitled to confidential treatment\*

APR 9 2002

W. A. Hawkins, Jr., Ph.D.  
Griffin L.L.C.  
P.O. Box 1847  
Valdosta, GA 31603-1847

Dear Dr. Hawkins:

Subject: Alternate Confidential Statement of Formula  
Fluridone Technical  
EPA Registration No. 1812-436  
Your Submissions Dated November 16, 2001 and April 3, 2002

The Agency has reviewed your submissions for the Confidential Statement of Formula for the alternate formulation, and the following comments apply:

The Confidential Statement of Formula dated November 6, 2001 for the alternate formulation agrees with the label claim in compliance with PR Notice 91-2 and is acceptable, provided that an acceptable five-batch analysis conducted on the formulation produced in the production facility in [REDACTED] is submitted within one year of the date of this letter.

We will await the submission of the required information as described above. The Confidential Statement of Formula has been added to your file as part of the record.

Sincerely yours,

Joanne I. Miller  
Product Manager (23)  
Herbicide Branch  
Registration Division (7505C)

DK: 305-7546: HB/PM 23

CONCURRENCES

SYMBOL	7505C							
SURNAME	D. KENNY							
DATE	4/9/2002							





## Fluridone Technical

### EPA Registration No. 1812-436

#### Note To The File

April 9, 2002

The Confidential Statement of Formula (CSF) dated November 12, 2001 for the alternate formulation was reviewed on the PM Team by Dan Kenny. The CSF was submitted in order to revise locations of the production facility. The actual formulation and all other information is said by the company to remain completely unchanged from the previously approved basic formulation dated November 23, 1999. In a supplemental submission (dated April 3, 2002), Griffin has certified that the manufacturing process is identical, and includes exactly the same ingredients as the basic formulation from exactly the same source companies. They have also cited the product chemistry data from the basic formulation, since they are claiming that the formulations are identical.

Review of the CSFs reveals that the alternate CSF was filled out exactly the same as the basic formulation. In a meeting between Dan Kenny (RD/HB) and Shyam Mathur (RD/TRB) on April 9, 2002, it was determined that, since Griffin has certified that this formulation is 100% identical in every respect (other than the actual physical location of production) as the basic formulation, the Agency will accept the proposed alternate formulation **on the condition that a five-batch analysis is submitted** for verification purposes.

Conclusion: The CSF dated November 12, 2001 for the basic formulation is **conditionally acceptable**.

A handwritten signature of Dan Kenny in black ink, written over a light blue circular stamp.

Dan Kenny (RD/HB/PM23)

4/9/2002



\*Product ingredient source information may be entitled to confidential treatment\*



VIA FACSIMILE

April 3, 2002

Mr. Daniel C. Kenny  
Registration Division  
Office of Pesticide Programs (7504C)  
U.S. Environmental Protection Agency  
Room 266A, Crystal Mall 2  
1921 Jefferson Davis Highway  
Arlington, Virginia 22202-4501

Dear Mr. Kenny:

**SUBJECT: FLURIDONE TECHNICAL (EPA REG. NO. 1812-436)  
AMENDED CONFIDENTIAL STATEMENT OF FORMULA  
ALTERNATIVE PRODUCTION FACILITY  
OPP IDENTIFICATION NUMBER 270582**

This letter is a follow-up to Griffin's submission dated November 16, 2001 and my subsequent telephone conversation with you on March 12, 2002. Griffin intends to produce Fluridone Technical at [REDACTED]

[REDACTED] facility is a registered pesticide producing establishment (EPA [REDACTED])

Fluridone production at the [REDACTED] facility will utilize a manufacturing process that is identical to the one described in the following study that was submitted to support the original registration of this product, including exactly the same components from the identical sources.

Griffin Technical Fluridone – Product Identity and Composition, MRID # 44983801

Should you require any additional information, please contact me at 229-293-4242, Extension 1104.

GRIFFIN L.L.C.

A handwritten signature in cursive script that reads "W. A. Hawkins, Jr.".

W. A. Hawkins, Jr., Ph.D.  
Senior Registration Manager,  
Copper Products, Insecticides and State Affairs

Griffin L.L.C.

P.O. Box 1847 • Valdosta, GA 31603-1847  
2509 Rocky Ford Rd. • Valdosta, GA 31601  
Telephone: (229) 242-8635  
Facsimile: (229) 244-5813



## TELEFAX TRANSMISSION

CONFIDENTIALITY NOTE: The documents accompanying this fax transmission may contain information which is confidential or privileged. The information is intended for the use of the individual or entity to whom it is directed. If you are not the intended recipient, be aware that any disclosure, copying, distribution, or use of the contents or the faxed information is prohibited. If you have received this fax in error, please notify us by telephone immediately so that we can arrange for the retrieval of the original documents at no cost to you.

DATE:

4/3/02

COMPANY:

EPA/OPP/RD

ATTENTION:

Dan Kenny

FROM:

ALEX HAWKINS

THE FOLLOWING MESSAGE CONSISTS OF 2 PAGE(S), INCLUDING THIS COVER SHEET.

IF YOU DO NOT RECEIVE ALL THE PAGES, PLEASE CALL ALEX HAWKINS AT (229) 293-4242, Ext. 1104. SENT FROM FAX NUMBER (229) 244-5978.

COMMENTS:

Letter you requested re: Fluridone Technical  
(EPA Reg. No. 1812-436).

Alex Hawkins

W. A. Hawkins, Jr., Ph.D.  
Registration Manager,  
Copper Products and State Affairs  
229-293-4242, Ext. 1104  
229-244-5978 (fax)  
alex.hawkins@griffinLLC.com

Griffin L.L.C.

P.O. Box 1847 / Valdosta, GA 31603-1847  
2509 Rocky Ford Rd. / Valdosta, GA 31601  
Telephone: (229) 242-8635  
Facsimile: (229) 244-5813



VIA UPS NEXT DAY AIR

November 16, 2001

Ms. Joanne I. Miller  
Document Processing Desk (AMEND)  
Office of Pesticide Programs (7504C)  
U.S. Environmental Protection Agency  
Room 266A, Crystal Mall 2  
1921 Jefferson Davis Highway  
Arlington, Virginia 22202-4501

Dear Ms. Miller:

**SUBJECT: FLURIDONE TECHNICAL (EPA REG. NO. 1812-436)  
AMENDED CONFIDENTIAL STATEMENT OF FORMULA  
ALTERNATIVE PRODUCTION FACILITY**

For a number of business reasons, Griffin intends to produce Fluridone Technical at [REDACTED] This facility is a registered pesticide producing establishment [REDACTED] In addition to the identity of the producer in Item #2 on EPA Form 8570-4, the EPA Registration Number has been added in Item #4 and the brand name in Item #3 has been updated per our earlier notification dated May 25, 2000. No other changes have been made.

Should you require any additional information, please contact me at 229-293-4242, Extension 1104.

GRIFFIN L.L.C.

*W. A. Hawkins, Jr.*

W. A. Hawkins, Jr., Ph.D.  
Registration Manager,  
Copper Products and State Affairs


Griffin L.L.C.

P.O. Box 1847 • Valdosta, GA 31603-1847  
2509 Rocky Ford Rd. • Valdosta, GA 31601  
Telephone: (229) 242-8635  
Facsimile: (229) 244-5813



Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060

	United States	<input type="checkbox"/> Registration <input checked="" type="checkbox"/> Amendment <input type="checkbox"/> Other	OPP Identifier Number
	Environmental Protection Agency		
	Washington, DC 20460		270582

### Application for Pesticide - Section I

1. Company/Product Number 1812-436	2. EPA Product Manager Joanne I. Miller	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Fluridone Technical	PM# 23	
5. Name and Address of Applicant (Include ZIP Code) Griffin L.L.C. P.O. Box 1847 Valdosta, GA 31603-1847 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____

### Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.


Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Alternative Confidential Statement of Formula: changes production location to [REDACTED]

### Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____	
* Certification must be submitted		If "Yes" Unit Packaging wgt. _____ No. per container _____	If "Yes" Package wgt. _____ No. per container _____		
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

### Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name W. A. Hawkins, Jr., Ph.D.	Title Registration Manager	Telephone No. (Include Area Code) 229-293-4242 x.1104	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped) _____	
2. Signature 	3. Title Registration Manager		
4. Typed Name W. A. Hawkins, Jr., Ph.D.	5. Date November 16, 2001		



## PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

**PAPERWORK REDUCTION ACT NOTICE:** Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, (2136), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460.

**INSTRUCTIONS:** This form is to be used for all applications for new registration, end use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Matrices where applicable.

**Submission of Labeling** - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed text on 8.5 x 11 inch paper for submission or a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

**Submission of Data** - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

**SPECIFIC INSTRUCTIONS:** Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

**Block A** - Check the appropriate action for which you are submitting this form.

**SECTION I** - This section must be completed, as applicable, for all registration actions.

1. **Company/Product Number** - Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. **EPA Product Manager** - If known, fill in the name and PM number of the EPA Product Manager.
3. **Proposed Classification** - Specify the proposed classification of this product.
4. **Product Name** - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. **Name and Address of Applicant** - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. **Expedited Review** - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

**SECTION II** - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. **Subject of submission** - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; "general label revision of use directions." Attach a separate page if additional space is needed.

**SECTION III** (Packaging and Containers Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. **Type of Packaging** - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. **Type of Retail Container** - Indicate type of container in which product will be marketed.
3. **Location of Net Contents** - Indicate the location of the net contents information for your product.
4. **Size(s) of Retail Container** - Specify the net contents of all retail containers for your product.
5. **Location of Use Directions** - Indicate the location of the use directions for your product.
6. **Manner in which label is affixed to product** - Indicate the method product label is attached to retail container.

**SECTION IV** (Comments) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too", reregistration, etc.

- 1-5. Self-explanatory.
6. EPA Use Only.





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

11/28/2001

W.A. HAWKINS, JR.  
GRIFFIN L.L.C.  
P.C. BOX 1847  
VALDOSTA GA 316031847

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

PRODUCT NAME: FLURIDONE TECHNICAL  
COMPANY NAME: GRIFFIN L.L.C.  
OPP IDENTIFICATION NUMBER: 270582  
EPA REGISTRATION NUMBER: 1812-436  
EPA RECEIPT DATE: 11/16/2001

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application qualifies for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability.

If you have any questions, please contact Joanne Miller, Product Manager 23, at (703)-305-6224.

Sincerely,

A handwritten signature in cursive script, appearing to read "Joanne".

Front End Processing Staff  
Information Services Branch  
Program Management and Support Division

## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

W. A. Hawkins, Jr., Ph.D.  
Griffin L.L.C.  
P.O. Box 1847  
Valdosta, GA 31603-1847

JAN 18 2002

Dear Dr. Hawkins:

Subject: Storage Stability and Corrosion Characteristics Studies  
Fluridone Technical  
EPA Registration No. 1812-436  
Your Submission Dated April 10, 2001

The Agency has reviewed the Storage Stability Study (§830.6317) and the Corrosion Characteristics Study (§830.6320) submitted as required by the Notice of Pesticide Registration dated March 15, 2000 for the product referenced above. It has been determined that the studies are acceptable to support the registration of this product. A complete copy of the review has been included with this letter for your information. No further product chemistry information is required for this product at this time.

Sincerely yours,

Joanne I. Miller  
Product Manager (23)  
Herbicide Branch  
Registration Division (7505C)

Enclosure

DK:305-7546:HB/PM23

## CONCURRENCES

SYMBOL ▶	7505C							
SURNAME ▶	D. KENNY							
DATE ▶	1/18/2002							



DATE OUT: 22 Aug 2001

SUBJECT: EP [ ] MP [x] PRODUCT CHEMISTRY REVIEW  
DP BARCODE No.: D275287  
REG./File Symbol No.: 1812-436  
PRODUCT NAME: Technical Fluridone  
COMPANY: Griffin LLC

TO: PM #23, Joanne Miller/Daniel Kenny  
Herbicide Branch  
Registration Division (7505C)

FROM: Bruce F. Kitchens, Chemist  
Technical Review Branch  
Registration Division (7505C)

*Bruce F. Kitchens*  
*22 Aug 2001*

**INTRODUCTION:**

The registrant, Griffin LLC, is submitting product chemistry data required as a condition of registration for the new manufacturing use product, Technical Fluridone. The active ingredient in this product is Fluridone (1-methyl-3-phenyl-5-[3-(trifluoromethyl)phenyl]-4(1H)-pyridinone) at a label nominal concentration of 99.2% a.i. and is intended for use as a herbicide manufacturing use product. In this submission, the registrant has submitted product chemistry data contained in MRID# 453871-01. This data is intended to satisfy the Storage Stability and Corrosion Characteristics data requirements. The Technical Review Branch (TRB) has been asked to review this submission.

**SUMMARY OF FINDINGS:**

TRB has reviewed this submission and reports the following findings:

1. The test substance used in this study was technical fluridone. The study was conducted for one year on five individual lots of the technical product. Samples were analyzed after one year storage at the twelve month interval. Samples were stored at ambient conditions. No other sample intervals were noted in the study.
2. Griffin analytical standard SAN 791 (fluridone, 99.4%) was used as the reference standard for the determination of the percent active ingredient.

3. The method employed in the determination of the active ingredient was Griffin test method TM-1235. Samples were analyzed in triplicate by Gas Liquid Chromatography. No additional details of the method were provided in the registrant's report.
4. Visual examination of the immediate package after storage at ambient temperature for one year revealed no corrosive interaction between the test material and its packaging. Composition of the packaging was not provided in the study report.
5. Post storage analysis of the five batches of technical fluridone yielded results ranging from 99.1 to 100.4% with an average of 99.3% active ingredient. Color and physical state remained unchanged.

#### CONCLUSIONS:

TRB has reviewed this submission and concludes the following:

1. The Storage Stability (830-6317) and the Corrosion Characteristics (830-6320) data requirements are satisfied.





453871-00

VIA UPS OVERNIGHT DELIVERY

April 10, 2001

Ms. Joanne I. Miller (23)  
Document Processing Desk  
Registration Division (H7504C)  
U.S. Environmental Protection Agency  
Room 266A, Crystal Mall 2  
1921 Jefferson Davis Highway  
Arlington, Virginia 22202-4501

Dear Ms. Miller:

**SUBJECT: FLURIDONE TECHNICAL (EPA REG. NO. 1812-436)  
SUBMISSION OF REQUIRED CORROSION STUDY**

When Fluridone Technical (EPA Reg. No. 1812-436) was granted conditional registration on March 15, 2000, Griffin was required to submit an acceptable one-year Corrosion Characteristics study (Guideline 830.6320) within two years of that date. Submitted herewith to satisfy that requirement are three separately bound copies of the following document:

<u>Guideline Number</u>	<u>Document Number</u>	<u>Name of Study</u>	
830.6317 and 830.6320	P99-026	Griffin Technical Fluridone Storage Stability	45387101

We hope that this study will be satisfactory to support continued registration of our product. Should you require any additional information, please contact me at 229-293-4242, Extension 1104.

Sincerely,

GRIFFIN L.L.C.

W. A. Hawkins, Jr., Ph.D.  
Registration Manager,  
Copper Products and State Affairs

Griffin L.L.C.

P.O. Box 1847 • Valdosta, GA 31602-1847  
2509 Rocky Ford Rd. • Valdosta, GA 31601  
Telephone: (912) 242-8635  
Facsimile: (912) 244-5813



U.S. ENVIRONMENTAL PROTECTION AGENCY  
Office of Pesticide Programs

APR 27 2001

GRIFFIN CORPORATION  
P.O. BOX 1847  
VALDOSTA, GA 316031847

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your transmittal of 04/13/01. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.





United States  
Environmental Protection Agency  
Washington, DC 20460

☐ Registration  
☐ Amendment  
☒ Other

OPP Identifier Number

270531

## Application for Pesticide - Section I

1. Company/Product Number 1812-436	2. EPA Product Manager Joanne L. Miller	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Fluridone Technical	PM# 23	
5. Name and Address of Applicant (Include ZIP Code) Griffin L.L.C. P.O. Box 1847 Valdosta, GA 31603-1847  <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

## Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input checked="" type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Submission of one-year Corrosion Characteristics study (Guideline 830.6320) as required by the terms of the Conditional Registration issued on March 15, 2000.

## Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must submitted	If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt. No. per container			
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container	5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product		
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			<input type="checkbox"/> Other _____		

## Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name W. A. Hawkins, Jr., Ph.D.		Title Registration Manager		Telephone No. (Include Area Code) 229-293-4242 x.1104	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received (Stamped) 
2. Signature 		3. Title Registration Manager			
4. Typed Name W. A. Hawkins, Jr., Ph.D.		5. Date April 10, 2001			

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## PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

**PAPERWORK REDUCTION ACT NOTICE:** Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, (2136), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460.

**INSTRUCTIONS:** This form is to be used for all applications for new registration, and use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Matrices where applicable.

**Submission of Labeling** - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission or a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

**Submission of Data** - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

**SPECIFIC INSTRUCTIONS:** Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

**Block A** - Check the appropriate action for which you are submitting this form.

**SECTION I** - This section must be completed, as applicable, for all registration actions.

1. **Company/Product Number** - Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. **EPA Product Manager** - If known, fill in the name and PM number of the EPA Product Manager.
3. **Proposed Classification** - Specify the proposed classification of this product.
4. **Product Name** - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. **Name and Address of Applicant** - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. **Expedited Review** - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

**SECTION II** - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. **Subject of submission** - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; "general label revision of use directions." Attach a separate page if additional space is needed.

**SECTION III** (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. **Type of Packaging** - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. **Type of Retail Container** - Indicate type of container in which product will be marketed.
3. **Location of Net Contents** - Indicate the location of the net contents information for your product.
4. **Size(s) of Retail Container** - Specify the net contents of all retail containers for your product.
5. **Location of Use Directions** - Indicate the location of the use directions for your product.
6. **Manner in which label is affixed to product** - Indicate the method product label is attached to retail container.

**SECTION IV** (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

- 1-5. Self-explanatory.
6. EPA Use Only.



APR 19 2001

U.S. ENVIRONMENTAL PROTECTION AGENCY  
Office of Pesticide Programs

GRIFFIN CORPORATION  
P.O. BOX 1847  
VALDOSTA, GA 316031847

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your transmittal of 04/13/01. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

We are unable to accept your data submittal for further processing and review, because of the significant deficiencies noted below. It is being returned to you for correction. If deficiencies were found which apply to your overall submission, they are described immediately following this paragraph. If problems are found with individual studies, they are described below linked to the study identifier found on the enclosed copy of your bibliography.

Rejected study [01] :

A statement of compliance or non-compliance with the Good Laboratory Practices Standards contained in 40 CFR160 is required for all studies (except range finding studies and supplements to previously submitted studies) submitted to EPA. This statement must appear as page 3 of all studies, and must be signed and dated by the study sponsor, the study submitter, and the study director. Please see 40 CFR 160.12 for specific guidance.





VIA UPS OVERNIGHT DELIVERY

April 10, 2001

Ms. Joanne I. Miller (23)  
Document Processing Desk  
Registration Division (H7504C)  
U.S. Environmental Protection Agency  
Room 266A, Crystal Mall 2  
1921 Jefferson Davis Highway  
Arlington, Virginia 22202-4501

Dear Ms. Miller:

**SUBJECT: FLURIDONE TECHNICAL (EPA REG. NO. 1812-436)  
SUBMISSION OF REQUIRED CORROSION STUDY**

When Fluridone Technical (EPA Reg. No. 1812-436) was granted conditional registration on March 15, 2000, Griffin was required to submit an acceptable one-year Corrosion Characteristics study (Guideline 830.6320) within two years of that date. Submitted herewith to satisfy that requirement are three separately bound copies of the following document:

<u>Guideline Number</u>	<u>Document Number</u>	<u>Name of Study</u>
830.6317 and 830.6320	P99-026	Griffin Technical Fluridone Storage Stability

Reject (01)

We hope that this study will be satisfactory to support continued registration of our product. Should you require any additional information, please contact me at 229-293-4242, Extension 1104.

Sincerely,

GRIFFIN L.L.C.

*W. A. Hawkins, Jr.*

W. A. Hawkins, Jr., Ph.D.  
Registration Manager,  
Copper Products and State Affairs

Griffin L.L.C.

P.O. Box 1847 • Valdosta, GA 31602-1847  
2509 Rocky Ford Rd. • Valdosta, GA 31601  
Telephone: (912) 242-8635  
Facsimile: 912-244-5813





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

NOV 26 2001

I, Joanne I. Miller, Product Manager of Team Number 23, Herbicide Branch, Registration Division, Office of Pesticide Programs, Office of Prevention, Pesticides and Toxic Substances, United States Environmental Protection Agency ("EPA"), certify that the pesticide product (s) listed below is, as of the date of this letter, a registered product under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, and that as such, the product(s) may be sold and marketed in the United States of America as authorized and limited by FIFRA. A true and correct copy of the product label approved by EPA is attached to accompany this letter.

Registration of this product(s) with EPA also denotes that the registrant listed below is responsible for ensuring full compliance with all the laws of the United States of America, or governing jurisdiction, regarding the sale, storage and/or disposal of the product(s). Further, the recipient of this letter is on notice that the referenced registration and/or the accompanying label may change subsequent to the date of this letter. EPA assumes no responsibility to notify the recipient of this letter of any change in the status of the registration(s) and/or the product label for the product(s) listed below.

EPA has issued registration number(s) for the product(s) listed below to:

Griffin L.L.C.  
P.O.Box 1847  
Valdosta, Georgia 31603-1847

Name of Product	<u>EPA Reg No</u>
TECHNICAL FLURIDONE	1812-436

*Joanne I. Miller*

Joanne I. Miller  
Product Manager (23)  
Herbicide Branch  
Registration Division (7505C)





SEP 27 2000

Steve D. Cockreham, Ph.D.  
SePRO Corporation  
11550 North Meridian Street  
Suite 600  
Carmel, IN 46032-4565

Dear Dr. Cockreham:

Subject: Griffin's Fluridone Technical  
EPA Registration No. 1812-436  
Your Letter Dated August 22, 2000

Thank you for your letter, referenced above, expressing concern over the registration of a technical fluridone product by Griffin L.L.C. You indicated that EPA registered this product in error, since a product chemistry review from the Technical Review Branch (TRB) in the Registration Division concluded that the proposed technical was not substantially similar to SePRO's registered technical. The Similarity Clinic of TRB, however, concluded that the Griffin technical was substantially similar to the SePRO technical. You also stated that based upon the product chemistry review, the Agency did not have adequate data to make a determination that the Griffin technical would not cause unreasonable adverse effects to the environment.

Upon receipt of your letter, I re-examined our records of Griffin's Fluridone Technical Section 3 registration. You are correct in pointing out to us the "apparent" contradiction in conclusions from the product chemistry review and Similarity Clinic determination from TRB. When there are different determinations within the TRB, the final determination is made on the Product Management (PM) Team and it is usually **documented** as part of our record. Unfortunately, this documentation was not done for Griffin's Fluridone Technical.

In response to your letter, I asked TRB to clarify their position on the substantial similarity claim of Griffin. After re-evaluating the Section 3 application, TRB concluded that while, from a product chemistry viewpoint the two technicals are not similar, from a toxicological viewpoint, both technicals are similar.

Under FIFRA Section 3(c)(7)(A), Registration Under Special Circumstances, the Administrator may conditionally register a pesticide if "(i) the pesticide and proposed use are identical or substantially similar to any currently registered pesticide and use thereof, or differ only in ways that would not significantly increase the risk of unreasonable adverse effects on the

## CONCURRENCES

SYMBOL ▶	7505C							
SURNAME ▶	JIMiller							
DATE ▶	Sep 27, 2000							



environment." We have determined that while there is a slight difference in the impurity profile between the two technicals, this difference will not **significantly increase the risk of unreasonable adverse effects** on the environment. Therefore, our decision to register Griffin's fluridone technical was appropriate.

Griffin's product chemistry data package was reviewed and determined to be acceptable. Griffin satisfied the data compensation requirements as specified in 40 CFR Part 152, Subpart E. The company used the "Cite-All" option and signed the general offer to pay statement. Griffin's Fluridone Technical was registered under FIFRA Section 3(c)(7)(A) and I am convinced that the requirements for a section 3 registration were met.

I appreciate your bringing this matter to my attention. If you have any further questions, I can be reached at (703) 305-6224.

Sincerely yours,

Joanne I. Miller  
Product Manager 23  
Herbicide Branch  
Registration Division (7505C)



SePRO Corporation • 11550 North Meridian Street • Suite 600 • Carmel, Indiana 46032-4565  
Phone: (317) 580-8282 • Fax: (317) 580-8280

---

August 22, 2000

**By Telecopy**

Ms. Joanne I. Miller  
Product Manager (23)  
Registration Division (7505C)  
United States Environmental Protection Agency  
1921 Jefferson Davis Highway  
Arlington, Virginia 22202

Re: Griffin Technical Fluridone

Dear Joanne:

I am writing to bring to your attention, and ask that the Environmental Protection Agency promptly correct, an apparent error on its part in issuing a registration to Griffin L.L.C. for technical fluridone. Documents obtained under the Freedom of Information Act show that EPA's Technical Review Branch concluded that Griffin's technical fluridone "can not to [sic] be considered substantially similar to the registered product Sonar technical (Reg. No. 67690-6) from the chemical composition point of view."<sup>1</sup> Given EPA's conclusion regarding the composition of Griffin's product, Griffin cannot rely upon SePRO's extensive data base submitted to EPA in support of fluridone's registration, and Griffin's application for registration is not properly supported by data that would allow EPA to conclude that Griffin's technical fluridone will not cause unreasonable adverse effects to the environment.

SePRO is deeply concerned that EPA is permitting distribution of a fluridone product that is not substantially similar to SePRO's. This means, in a practical sense, that Griffin's product is untested. EPA should require that Griffin submit data demonstrating the substantial similarity of its technical fluridone to SePRO's Sonar technical as a condition of the continued registration of Griffin's product. Griffin should not be permitted to distribute any fluridone product until Griffin can demonstrate that its product is substantially similar to SePRO's. Unless Griffin can make the required showing of substantial similarity, EPA should withdraw the registration that it issued to Griffin in apparent error.

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<sup>1</sup> Sonar is a registered trademark of SePRO Corporation.



Ms. Joanne I. Miller  
August 22, 2000  
Page 2

*Substantial Similarity of Products for Me-Too Registration*

Under EPA's regulation governing registration of a product that does not contain a new active ingredient it states that the Agency will not approve the registration "unless the Agency has determined that the applicant's product and its proposed use are identical or substantially similar to a currently registered pesticide and use." 40 C.F.R. § 152.113. I understand that EPA makes two determinations regarding the substantial similarity of a product for purposes of a me-too registration. The Similarity Clinic Determination decides whether a me-too product is substantially similar to an existing product solely for purposes of whether the products share similar acute toxicity characteristics and should bear the same precautionary and first aid statements as the cited product. The Product Chemistry Team, on the other hand, conducts a separate, and more significant, review which determines whether the chemical composition of the me-too product is substantially similar for purposes of allowing the me-too registrant to rely on the data submitted to EPA in support of the registration for the existing product. This is consistent with our prior discussions concerning how EPA evaluates a substantial similarity claim by a me-too registrant.

In the registration file for Griffin's technical fluridone, there is a memo dated March 2, 2000 addressed from Shyam Mathur (Chemist)(Attachment 1) which provides the Product Chemistry Team's review of Griffin's technical fluridone. This product chemistry review states that the fluridone technical proposed for registration by Griffin "can not to [sic] be considered substantially similar to the registered product Sonar technical (Reg. No. 67790-6) from the chemical composition point of view." The memo also refers to changes in the physical-chemical properties of Griffin's product that would have resulted from changes in the chemical composition. Because the memo does not elaborate on the nature of the changes in the chemical composition of Griffin's technical fluridone, SePRO cannot speculate on how Griffin's technical fluridone may differ from Sonar. However, it is not surprising that there would be differences between Griffin's new technical fluridone and SePRO's Sonar technical, arising from the complexity of manufacturing fluridone. It is clear that the Product Chemistry Team has identified specific questions that must be resolved concerning Griffin's technical fluridone product before it can be registered by citing SePRO's data. Because this conclusion appears within the body of the memo, it seems possible that it was overlooked when EPA issued to Griffin a registration for technical fluridone.

In issuing Griffin's registration, EPA may have relied by mistake on the Similarity Clinic Determination of substantial similarity dated March 3, 2000. (Attachment 2). At that time, the Similarity Clinic found that Griffin's technical fluridone product is substantially similar to Sonar, but only for purposes of assessing the acute toxicity of the Griffin product. This limited assessment does not provide an adequate basis for EPA's decision to register Griffin's product



Ms. Joanne I. Miller  
August 22, 2000  
Page 3

based on SePRO's fluridone data. It is simply not clear that SePRO's fluridone data is relevant to, or sufficient for, assessing the risks posed by Griffin's technical fluridone.

Under these circumstances, EPA would be expected ordinarily to obtain from the applicant for registration additional information to resolve these conflicts concerning the comparison of Griffin's technical fluridone to Sonar technical. In this case, it does not appear possible for Griffin to have submitted additional data resolving this conflict. The Product Chemistry Team's memo concluding that Griffin's product is not substantially similar to Sonar is dated March 2, 2000. By March 15, 2000, EPA issued to Griffin its conditional registration. There is nothing in the Griffin registration files, to the extent provided to SePRO under FOIA, suggesting that Griffin submitted any additional data or information. SePRO concludes, therefore, that EPA decided apparently in error to issue to Griffin a conditional registration for its proposed technical fluridone product and that the error arose due to a simple oversight. This can and should be readily corrected.

#### *Distribution of Griffin's Product Poses Potential Health and Environmental Concerns*

Griffin's distribution of its fluridone product poses potential health and environmental concerns because Griffin's technical fluridone is not demonstrated to be substantially similar to Sonar technical. It is possible that Griffin's technical fluridone may differ from Sonar in its environmental fate or effects, or in its long term toxicity characteristics. If Griffin's technical fluridone is not substantially similar to Sonar, it is simply untested. SePRO believes that EPA should resolve these questions promptly.

Sonar is, as you know, an aquatic herbicide. Based on the toxicological profile of Sonar technical, fluridone products are applied in lakes and reservoirs serving as sources of potable water. EPA has registered Sonar and Griffin's new fluridone products without restrictions on the use of treated water for fishing and swimming. Thus, there may be very substantial human exposure to water treated with Griffin's fluridone products. If any adverse environmental or health effects were to result from the use of Griffin's fluridone product, EPA or the public may attribute those affects to fluridone itself. EPA will have no way, however, of distinguishing effects that may result from the distinct composition or characteristics of Griffin's technical fluridone. SePRO is legitimately concerned that the reputation of its fluridone products may be tarred unfairly and inaccurately, as a result of harm that may be caused by Griffin's fluridone product of differing chemical composition.



Ms. Joanne I. Miller

August 22, 2000

Page 4

***EPA Should Resolve Immediately Questions Concerning the Composition of Griffin's Technical Fluridone***

It seems only logical that EPA should correct immediately the apparent error in issuing to Griffin a registration for its technical fluridone product. Since Griffin's technical fluridone is not substantially similar to Sonar technical, EPA should withdraw the registration that has been issued to Griffin by mistake. It is within EPA's authority to correct its own errors such as this one. At a minimum, EPA should request that Griffin refrain voluntarily from distributing any fluridone products until Griffin demonstrates to EPA that its product is substantially similar to SePRO's Sonar. If Griffin cannot show that its technical fluridone is substantially similar to Sonar technical, Griffin must satisfy independently the data requirements that apply to an aquatic herbicide registered under the same terms as technical fluridone.

I note that if EPA permits Griffin to retain a registration for technical fluridone, Griffin remains liable to compensate SePRO for reliance on its fluridone data. While there are questions concerning the substantial similarity of Griffin's technical fluridone to SePRO's existing Sonar technical product, SePRO's fluridone data is the only data set available to satisfy the requirements for environmental, health, and safety data that apply to Griffin's technical fluridone product.

***Conclusion***

For the reasons discussed above, SePRO requests that EPA act immediately to withdraw the registration for technical fluridone issued erroneously to Griffin. SePRO also requests that EPA require Griffin to submit data demonstrating its claims (1) that Griffin's technical fluridone is substantially similar to SePRO's Sonar technical product and (2) that Griffin is entitled to rely on SePRO's Sonar technical data to support Griffin's application to register a technical fluridone product.

Ms. Joanne I. Miller

August 22, 2000

Page 5

If you have any questions about SePRO's requests or their basis, please let me know.  
Thank you for your attention to this urgent matter.

Sincerely,

*Steve Cockreham /MRN*

Steve D. Cockreham, Ph.D.

Vice President, Research and Regulatory Affairs

cc: Mr. Donald Stubbs  
Ms. Diane Allemang  
Michael R. Neilson, Esq.

O:\CLR\ZZ\42\10686\Letter\MRN 2 SePRO Letter to Joanne Miller.wpd



## ATTACHMENT 1

02/MAR/2000

SUBJECT: Product Chemistry Review of Technical Fluridone (MP)

FROM: Shyam Mathur, Chemist  
Product Chemistry Team  
Technical Review Branch/RD (7505C)*S. Mathur*  
03-02-00TO: Joanne Miller, PM 23  
Herbicide Branch/ RD (7505C)DP BARCODE: D262770  
EPA REG. NO.: 1812-UGA  
REGISTRANT: Griffin L.L.C  
USE: Herbicide

## INTRODUCTION:

The Applicant has submitted product chemistry data to support the registration of the Technical Fluridone. This technical is a manufacturing use product to be used only in formulation of herbicide products used for aquatic weed control in fresh water ponds, lakes, reservoirs, drainage canals, irrigation canals and rivers.

## SUMMARY OF FINDINGS:

1. The data submitted corresponding to guideline reference 830.1550(Product identity, composition) satisfy the data requirements of 40CFR§158.155.
2. The data submitted corresponding to guideline reference 830.1600 (Description of material used in process), 830.1650(Production process), and 830.1670(Discussion on the formation of impurities) satisfy the data requirements of, 158.160, 158.162, and 158.167 respectively.
3. The data submitted corresponding to guideline reference 830.1700 (Preliminary analysis), 830.1750 (certified limits) and 830.1800 (Analytical methods to verify certified limits) satisfy the data requirements of 40CFR §158.170, 158.175 and 158.180 respectively.
4. The data submitted corresponding to guideline reference 830 Series Subgroup B(Physical-Chemical) properties for Fluridone technical satisfy the data requirements of 40CFR§158.190 and are acceptable.



CONCLUSION:

The TRB has reviewed the product chemistry data submitted for the Fluridone technical(MP) and has concluded that:

1. The data submitted corresponding to guideline reference 830.1550(Product identity, composition) satisfy the data requirements of 40CFR§158.155 and are acceptable.
2. The basic formulation CSF(dated 11-23-99)is filled out correctly and completely in compliance with PR Notice 91-2. The CSF for basic formulation dated 11-23-99 is acceptable.
3. The data submitted corresponding to guideline reference 830.1600 (Description of material used in process), 830.1650(Production process), and 830.1670(Discussion on the formation of impurities) satisfy the data requirements of 40CFR§158.160, 158.162, and 158.167 respectively and are acceptable.
4. The data submitted corresponding to guideline reference 830.1700(Preliminary analysis), and 830.1800 (Analytical methods to verify certified limits) satisfy the data requirements of 40CFR §158.170, and 158.180 respectively and are acceptable.
5. The product chemistry data submitted corresponding to Series 830 Subgroup B(Physical-Chemical properties) for the technical Fluridone satisfy the data requirements of 40CFR §158.190 and are acceptable. Except for 830.6320(Corrosion characteristics); the registrant is required to submit the results of one year study to be carried out along with one year storage stability. Two weeks study is not sufficient to make any evaluation.
6. The registrant must submit the proposed new method for the analysis of Fluridone technical to the EPA Analytical laboratory at Ft. Meade, MD, for validation.
7. The Fluridone technical(Reg. No. 1812-UGA) can not to be considered substantially similar to the registered product Sonar technical(Reg. No. 67690-6) from the chemical composition point of view. Since the physical-chemical properties of the proposed product have changed with the change in the chemical composition.



## REVIEW OF PRODUCT CHEMISTRY, OPPTS 830 SERIES

Chemical Name (IUPAC, ANSI, etc.)	1-methyl-3-phenyl-5'[(3-trifluoromethyl)phenyl]-4-(1H)-pyridone
Chemical Numbers (CAS; PC Code)	Reg. No. 1812-UGA CAS No. 59756-60-4 PC Code: 112900
Registration/Symbol No./Petition No.	1812-UGA
Type of Product (T, FI, MP, EP)	99.2 % T(MP)
DP Barcode	D262770
Reviewer	Shyam Mathur, Ph.D

Griffin LLC., has submitted product chemistry data for Fluridone technical(MP) to support its registration.

Table 1: Manufacturing and Impurity Data for the Oxytetracycline dihydrate TGA/MP				
GLN	Requirement	MRID	Status <sup>1</sup>	Details and/or Deficiency <sup>2</sup>
830.1550	Product Identity & Disclosure of Ingredients	CSF dated 11-23-99	A	the basic formulation CSF with NC, upper and lower certified limits of AI provided. NC concur with label claim nominal concentration. The reported impurities which are present at a level of [REDACTED] and therefore listed in CSF.
830.1600 830.1620 830.1650	Starting Materials & Manufacturing Process	449838-01	A	All the information is provided on the starting materials including name of suppliers, chemical names, CAS numbers, Phys-chem properties, etc. Details are provided on manufacturing process along with chemical equations..
830.1670	Discussion of Impurities	449838-01	A	Discussion of impurities in materials used to produce the product, side reaction products and impurities due to post-production reactions or degradation are provided.
830.1700	Preliminary Analysis	449838-03 449838-04	A	Five batches of the technical were analyzed by GLC method No. TM-1235 and GC-MS method No. TM-1243. Both methods are validated for precision, accuracy, & linearity.
830.1750	Certification of Limits	CSF dated 11-23-99	A	NC, UCL & LCL of the AI and NC and UCL of the impurities are provided as per 40CFR158.175b2.
830.1800	Analytical Methods	449838-04	A	The GC-MS method was used for determination of the AI and all other [REDACTED] impurities.

<sup>1</sup> A = Acceptable; N = Unacceptable (see Deficiency); N/A = Not Applicable.  
<sup>2</sup> Refer to CBI Appendix A for details.

ATTACHMENT: CONFIDENTIAL APPENDIX



## ATTACHMENT 2



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES  
AND  
TOXIC SUBSTANCES

TECHNICAL REVIEW BRANCH  
SIMILARITY CLINIC DETERMINATION

03/MAR/2000

Subject: EPA Reg. No./File Symbol: 1812-UGA Technical Fluridone  
DP Barcode: D262771  
Case No: 065180  
PC Code: 112900

From: Eugenia McAndrew, Biologist *Em*  
Technical Review Branch *Scr*  
Registration Division (7505 C)

To: Daniel Kenny, PM Team 23  
Herbicide Branch  
Registration Division (7505 C)

Applicant: Griffin L.L.C.  
P.O. Box 1847  
Valdosta, Georgia 31603-1847

**ACTION REQUESTED:** TRB has been asked to determine if File Symbol No. 1812-UGA, Technical Fluridone, is substantially similar to EPA Reg. No. 67690-6, Sonar Technical.

**RECOMMENDATIONS:** We have evaluated the formulations of File Symbol No. 1812-UGA and EPA Reg. No. 67690-6 and have found them to be substantially similar. The new product should have the same precautionary and first aid statements as the cited product.

This memorandum pertains only to the decision concerning whether the subject product is similar to the cited product from an acute toxicological view point. For the purposes of this action, TRB has made no determination of the adequacy of the toxicological data base or the precautionary label of the cited product.





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF PREVENTION,  
PESTICIDES AND TOXIC  
SUBSTANCES

30/August/2000  
MEMORANDUM

Subject: Technical Fluridone  
EPA Reg. No.: 1812-436  
DP Barcode: D268677  
Case No: 065180  
PC Code: 112900 Technical Fluridone

From: John C. Redden, Team Leader  
Technical Review Branch  
Registration Division (7505C) *JCR*

To: Joanne Miller, PM 23  
Herbicide Branch  
Registration Division (7505C)

Applicant: Griffin L.L.C.  
P.O. Box 1847  
Valdosta, Georgia

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>% by wt.</u>
Fluridone	99.2%
<u>Inert Ingredient(s):</u>	<u>0.8%</u>
Total:	100%



**ACTION:**

This is a revisit of the previous substantial similarity determination (D262771; Eugenia McAndrew; 03/MAR/2000). The PM requests:

"Please review and compare the CSFs of 1812-436 and 67690-6 for substantial similarity. Griffin claimed that their technical was substantially similar to DePros's technical and Griffin took CITE-ALL to fulfill the data compensation requirements. IF Griffin's technical is NOT substantially similar to SePro's technical, would Griffin's technical as registered, significantly increase the risk of unreasonable adverse effects on the environment. You are referred to the provisions of Registration Under Special Circumstances in FIFRA section 3 (c) (7) (A)...SePro submitted a letter to EPA, Challenging our registration decision of 1812-436."

**BACKGROUND:**

On 3/MAR/2000, TRB determined that EPA Reg. No. 1812-436, Technical Fluridone, was substantially similar to EPA Reg. No. 67690-6, Sonar Technical.

TRB notes that the two technicals have the same percentage of active ingredient (99.2). The impurities differ slightly between the two technicals, but in TRB's judgement this does not enhance the toxicity of EPA Reg. No. 1812-436. Therefore from a **Toxicology** point of view the two are similar. However, from a product chemistry point of view the two technicals are not similar.

Further, Griffin used cite all, in this registration matter. Their cite all, in TRB's opinion, cites the entire database (i.e. the database that registered EPA Reg. No. 67690-6, Sonar Technical).

TRB has concluded, that since the two technicals are identical in concentration and differ only slightly in the number of impurities, that there is no indication that there would be a significant increase or unreasonable adverse effects to the environment.

**CONCLUSION:**

For the reasons cited in the previous paragraphs, TRB stands by the 03/MAR/2000 Memorandum, which concluded that EPA Reg. No. 1812-436 is substantially similar to EPA Reg. No. 67690-6.



JUL 3 2000

Mr. W. A. Hawkins, Jr.  
Registration Manager  
GRIFFIN L.L.C.  
P.O. Box 1847  
Valdosta, GA 31603-1847

Dear Mr. Hawkins:

This is in response to your request dated May 25, 2000 to change the primary brand name for **EPA Registration 1812-436** from Technical Fluridone to:

**Fluridone Technical**

Your request for the name change **is accepted** and the change will be made to the Agency's records. All future correspondence on this product should reference the new name.

Sincerely yours,

/s/

Sherada D. Hobgood  
Notifications Review Coordinator  
Registration Division (7505C)





United States  
**Environmental Protection Agency**  
 Washington, DC 20460

☐ Registration  
☐ Amendment  
☒ Other

OPP Identifier Number

**Application for Pesticide - Section I**

1. Company/ Product Number 1812-436	2. EPA Product Manager Joanne I. Miller	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/ Product (Name) Technical Fluridone	PM# 23	
5. Name and Address of Applicant (Include ZIP Code) Griffin L.L.C. P.O. Box 1847 Valdosta, Georgia 31603-1847 <input type="checkbox"/> Check if this is a new address	6. <b>Expedited Review.</b> In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to:  EPA Reg. No. _____ Product Name _____	

**Section II**

- ☐ Amendment - Explain below. ☐ Final printed labels in response to Agency letter dated \_\_\_\_\_
- ☐ Resubmission in response to Agency letter dated \_\_\_\_\_ ☐ "Me Too" Application.
- ☒ Notification - Explain below. ☐ Other - explain below.

**Explanation:** Use additional page(s) if necessary. (For section I and Section II.)**Notification of change of primary brand name to Fluridone Technical per PR Notice 98-10.**

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

**Section III****1. Material This Product Will Be Packaged In:**

Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* <b>Certification must be submitted.</b>		If "Yes," Unit Package wgt. _____ No. per container _____	If "Yes," Package wgt. _____ No. per container _____

3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) of Retail Container	5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product
6. Manner In Which Label Is Affixed To Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Other _____ <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		

**Section IV****1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)**

Name W. A. Hawkins, Jr.	Title Registration Manager	Telephone No. (Include Area Code) 912-293-4242 Ext. 1104
----------------------------	-------------------------------	---

**Certification**

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

**6. Date Application Received**

(Stamped)

2. Signature 	3. Title Registration Manager	
4. Typed Name W. A. Hawkins, Jr.	5. Date May 25, 2000	



NOTIFICATION  
JUL 3 2000

05/25/00

## FLURIDONE TECHNICAL

g436n00a

For Manufacturing Use Only

### Active Ingredient

#### Fluridone:

1-methyl-3-phenyl-5-[3-(trifluoromethyl)phenyl]-4(1*H*)-pyridinone. . . . . 99.2%

Inert Ingredients . . . . . 0.8%

Total. . . . . 100.0%

### KEEP OUT OF REACH OF CHILDREN

## WARNING

### STATEMENT OF PRACTICAL TREATMENT

**IF IN EYES:** Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get medical attention.

**IF ON SKIN:** Wash with plenty of soap and water. Get medical attention if irritation persists.

**IF SWALLOWED:** Call a doctor or get medical attention. Do not induce vomiting or give anything by mouth to an unconscious person. Drink promptly a large quantity of milk, egg whites, gelatin solution, or if these are not available, drink large quantities of water. Avoid alcohol.

**IF INHALED:** Remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth-to-mouth. Get medical attention.

**NOTE TO PHYSICIAN:** Probable mucosal damage may contraindicate the use of gastric lavage.

**For medical emergencies involving this product, call toll free 1-888-324-7598.**

See Label for Additional Precautions and Directions for Use.

Griffin L.L.C.  
Valdosta, GA 31601

EPA Reg. No. 1812-436  
EPA Est. No.

Net Contents \_\_\_\_\_

**PRECAUTIONARY STATEMENTS**  
**HAZARDS TO HUMANS AND DOMESTIC ANIMALS**  
**WARNING**

Causes substantial but temporary eye injury. Harmful if swallowed, absorbed through skin or inhaled. Do not get in eyes, on skin or on clothing. Avoid breathing dust. Wear goggles, face shield or safety glasses when handling. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

**ENVIRONMENTAL HAZARDS**

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

**DIRECTIONS FOR USE**

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

**STORAGE AND DISPOSAL**

Do not contaminate water, food or feed by storage or disposal.

**STORAGE:** Store in original container only. In case of leak or spill, sweep up excess material and dispose of as waste.

**PESTICIDE DISPOSAL:** Wastes resulting from use of this product may be used according to label directions or disposed of at an approved waste disposal facility.

**CONTAINER DISPOSAL:** Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into formulation equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused, dispose of in the same manner.

**For Manufacturing Use Only in Formulating EPA Approved Herbicide Products:** This product may be used only in formulation of herbicide products used for aquatic weed control in fresh water ponds, lakes, reservoirs, drainage canals, irrigation canals and rivers.



## WARRANTY STATEMENT

GRIFFIN warrants that this product conforms to the chemical description on the label thereof and is reasonably fit for purposes stated on such label only when used in accordance with directions under normal use conditions. It is impossible to eliminate all risks inherently associated with use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of GRIFFIN. In no case shall GRIFFIN be liable for consequential, special or indirect damages resulting from the use or handling of this product. All such risks shall be assumed by the Buyer. The exclusive remedy of any buyer or user of this product for any and all losses, injuries, or damages resulting from or in any way arising from the use, handling or application of this product, whether in contract, warranty, tort, negligence, strict liability or otherwise, shall not exceed the purchase price paid for this product or at GRIFFIN'S election, the replacement of this product. GRIFFIN MAKES NO WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS STATED ABOVE.

Griffin and Design are a registered trademark of Griffin Corporation.

[Based on the EPA stamped accepted label (with comments) dated March 15, 2000]



VIA CERTIFIED MAIL

May 25, 2000

Ms. Sherada Hobgood  
Document Processing Desk (NOTIF)  
Office of Pesticide Programs (7504C)  
U.S. Environmental Protection Agency  
Ariel Rios Building  
1200 Pennsylvania Avenue, N.W.  
Washington, D.C. 20460-0001

Dear Ms. Hobgood:

**SUBJECT: NOTIFICATION – TECHNICAL FLURIDONE (EPA REG. NO. 1812-436)  
CHANGE PRIMARY BRAND NAME TO FLURIDONE TECHNICAL**

This is to notify the Agency that Griffin wishes to change the primary brand name of Technical Fluridone (EPA Reg. No. 1812-436) to Fluridone Technical. This change can be made by notification per PR Notice 98-10. One copy of an amended label reflecting this change is enclosed. No other changes have been made.

Should you require any additional information, please contact me at 912-293-4242, Extension 1104.

GRIFFIN L.L.C.

A handwritten signature in cursive script, reading "W. A. Hawkins, Jr.".

W. A. Hawkins, Jr., Ph.D.  
Registration Manager, Copper Products  
and State Affairs



Griffin L.L.C.

P.O. Box 1847 • Valdosta, GA 31603-1847  
2509 Rocky Ford Rd. • Valdosta, GA 31601  
Telephone: (912) 242-8635  
Facsimile: 912-244-5813





U.S. ENVIRONMENTAL PROTECTION AGENCY  
Office of Pesticide Programs  
Registration Division (7505C)  
401 "M" St., S.W.  
Washington, D.C. 20460

EPA Reg.  
Number:

1812-436

Date of Issuance:

MAR 15 2000

NOTICE OF PESTICIDE:

☒ Registration  
☐ Reregistration

(under FIFRA, as amended)

Term of Issuance:

Conditional

Name of Pesticide Product:

Technical Fluridone

Name and Address of Registrant (include ZIP Code):

Griffin L.L.C.  
P.O. Box 1847  
Valdosta, GA 31603-1847

**Note:** Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(A) provided that you:

1. Submit and/or cite all data required for registration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under FIFRA section 4.

2. Make the following label changes before you release the product for shipment:

- a. Revise the EPA Registration Number to read, "EPA Reg. No. 1812-436".
- b. Add a Note to Physician to the end of the Statement of Practical Treatment to read "Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage."
- c. Since this product comes in the form of a solid as opposed to a liquid, revise the second sentence of the Storage section in the Storage and Disposal block to read "In case of leak or spill, sweep up excess material and dispose of as waste."

Signature of Approving Official:

Date:

MAR 15 2000



# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Page 2  
EPA Reg. No. 1812-436

3. Submit an acceptable Corrosion Characteristics study (830.6320) for the technical fluridone material (i.e., the source of the active ingredient) within two (2) years of the date of this Notice. We acknowledge that data corresponding to this requirement was previously submitted with the original application. However, the two week study that was submitted is not sufficient to make any evaluation. Therefore, a one-year Corrosion Characteristics study for the technical fluridone material must be performed and submitted.

4. The analytical methods used to evaluate the active ingredient (TM-1235; MRID# 449838-03) and impurities (TM-1243; MRID# 449838-04) must be successfully validated by the Office of Pesticide Programs' Analytical Chemistry Laboratory. The methods are being forwarded to the laboratory for evaluation, and you will be notified of the results of the evaluation once it is completed.

5. Submit one copy of the revised final printed label for the record before you release the product for shipment.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

Joanne I. Miller  
Product Manager (23)  
Herbicide Branch  
Registration Division (7505C)

Enclosure

DK:305-7546:HB/PM23				CONCURRENCES				
SYMBOL ▶	7505C							
SURNAME ▶	D. KENNY							
DATE ▶	3/15/2000							



12/03/99

## TECHNICAL FLURIDONE

For Manufacturing Use Only

gx648s99a

ACCEPTED  
with COMMENTS  
In EPA Letter Dated

MAR 15 2000

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act  
as amended, for the pesticide  
registered under EPA Reg. No.

1812-436

Active Ingredient

Fluridone:

1-methyl-3-phenyl-5-[3-(trifluoromethyl)phenyl]-4(1H)-pyridinone. . . . . 99.2%

Inert Ingredients . . . . . 0.8%

Total. . . . . 100.0%

**KEEP OUT OF REACH OF CHILDREN**

### WARNING

#### STATEMENT OF PRACTICAL TREATMENT

**IF IN EYES:** Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get medical attention.

**IF ON SKIN:** Wash with plenty of soap and water. Get medical attention if irritation persists.

**IF SWALLOWED:** Call a doctor or get medical attention. Do not induce vomiting or give anything by mouth to an unconscious person. Drink promptly a large quantity of milk, egg whites, gelatin solution, or if these are not available, drink large quantities of water. Avoid alcohol.

**IF INHALED:** Remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth-to-mouth. Get medical attention.

**For medical emergencies involving this product, call toll free 1-888-324-7598.**

See Label for Additional Precautions and Directions for Use.

Griffin L.L.C.  
Valdosta, GA 31601

EPA Reg. No. 1812-  
EPA Est. No.

Net Contents \_\_\_\_\_

Griffin L.L.C.

EPA Reg. No. 1812-xxx

File Name: GX648s99a

12/99

Page 1 of 3



**PRECAUTIONARY STATEMENTS  
HAZARDS TO HUMANS AND DOMESTIC ANIMALS  
WARNING**

Causes substantial but temporary eye injury. Harmful if swallowed, absorbed through skin or inhaled. Do not get in eyes, on skin or on clothing. Avoid breathing dust. Wear goggles, face shield or safety glasses when handling. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

**ENVIRONMENTAL HAZARDS**

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

**DIRECTIONS FOR USE**

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

**STORAGE AND DISPOSAL**

Do not contaminate water, food or feed by storage or disposal.

**STORAGE:** Store in original container only. In case of leak or spill, use absorbent materials to contain liquids and dispose as waste.

**PESTICIDE DISPOSAL:** Wastes resulting from use of this product may be used according to label directions or disposed of at an approved waste disposal facility.

**CONTAINER DISPOSAL:** Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into formulation equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused, dispose of in the same manner.

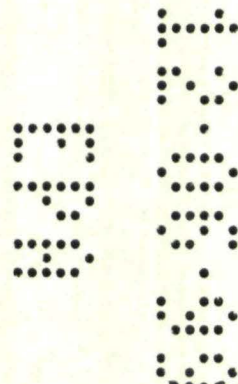
**For Manufacturing Use Only in Formulating EPA Approved Herbicide Products:** This product may be used only in formulation of herbicide products used for aquatic weed control in fresh water ponds, lakes, reservoirs, drainage canals, irrigation canals and rivers.



## WARRANTY STATEMENT

GRIFFIN warrants that this product conforms to the chemical description on the label thereof and is reasonably fit for purposes stated on such label only when used in accordance with directions under normal use conditions. It is impossible to eliminate all risks inherently associated with use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of GRIFFIN. In no case shall GRIFFIN be liable for consequential, special or indirect damages resulting from the use or handling of this product. All such risks shall be assumed by the Buyer. The exclusive remedy of any buyer or user of this product for any and all losses, injuries, or damages resulting from or in any way arising from the use, handling or application of this product, whether in contract, warranty, tort, negligence, strict liability or otherwise, shall not exceed the purchase price paid for this product or at GRIFFIN'S election, the replacement of this product. GRIFFIN MAKES NO WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS STATED ABOVE.

Griffin and Design are a registered trademark of Griffin Corporation.





02/MAR/2000

SUBJECT: Product Chemistry Review of Technical Fluridone (MP)

FROM: Shyam Mathur, Chemist  
Product Chemistry Team  
Technical Review Branch/RD (7505C)

*S. Mathur*  
03-02-00

TO: Joanne Miller, PM 23  
Herbicide Branch/ RD (7505C)

DP BARCODE: D262770  
EPA REG. NO.: 1812-UGA  
REGISTRANT: Griffin L.L.C  
USE: Herbicide

#### INTRODUCTION:

The Applicant has submitted product chemistry data to support the registration of the Technical Fluridone. This technical is a manufacturing use product to be used only in formulation of herbicide products used for aquatic weed control in fresh water ponds, lakes, reservoirs, drainage canals, irrigation canals and rivers.

#### SUMMARY OF FINDINGS:

1. The data submitted corresponding to guideline reference 830.1550(Product identity, composition) satisfy the data requirements of 40CFR§158.155.
2. The data submitted corresponding to guideline reference 830.1600 (Description of material used in process), 830.1650(Production process), and 830.1670(Discussion on the formation of impurities) satisfy the data requirements of, 158.160, 158.162, and 158.167 respectively.
3. The data submitted corresponding to guideline reference 830.1700 (Preliminary analysis), 830.1750 (certified limits) and 830.1800 (Analytical methods to verify certified limits) satisfy the data requirements of 40CFR §158.170, 158.175 and 158.180 respectively.
4. The data submitted corresponding to guideline reference 830 Series Subgroup B(Physical-Chemical) properties for Fluridone technical satisfy the data requirements of 40CFR§158.190 and are acceptable.



## CONCLUSION:

The TRB has reviewed the product chemistry data submitted for the Fluridone technical(MP) and has concluded that:

1. The data submitted corresponding to guideline reference 830.1550(Product identity, composition) satisfy the data requirements of 40CFR§158.155 and are acceptable.
2. The basic formulation CSF(dated 11-23-99)is filled out correctly and completely in compliance with PR Notice 91-2. The CSF for basic formulation dated 11-23-99 is acceptable.
3. The data submitted corresponding to guideline reference 830.1600 (Description of material used in process), 830.1650(Production process), and 830.1670(Discussion on the formation of impurities) satisfy the data requirements of 40CFR§158.160, 158.162, and 158.167 respectively and are acceptable.
4. The data submitted corresponding to guideline reference 830.1700(Preliminary analysis), and 830.1800 (Analytical methods to verify certified limits) satisfy the data requirements of 40CFR §158.170, and 158.180 respectively and are acceptable.
5. The product chemistry data submitted corresponding to Series 830 Subgroup B(Physical-Chemical properties) for the technical Fluridone satisfy the data requirements of 40CFR §158.190 and are acceptable. Except for 830.6320(Corrosion characteristics); the registrant is required to submit the results of one year study to be carried out along with one year storage stability. Two weeks study is not sufficient to make any evaluation.
6. The registrant must submit the proposed new method for the analysis of Fluridone technical to the EPA Analytical laboratory at Ft. Meade, MD, for validation.
7. The Fluridone technical(Reg. No. 1812-UGA) can not to be considered substantially similar to the registered product Sonar technical(Reg. No. 67690-6) from the chemical composition point of view. Since the physical-chemical properties of the proposed product have changed with the change in the chemical composition.



REVIEW OF PRODUCT CHEMISTRY, OPPTS 830 SERIES

Chemical Name (IUPAC, ANSI, etc.)	1-methyl-3-phenyl-5-[(3-trifluoromethyl)phenyl]-4-(1H)-pyridone
Chemical Numbers (CAS; PC Code)	Reg. No. 1812-UGA CAS No. 59756-60-4 PC Code: 112900
Registration/Symbol No./Petition No.	1812-UGA
Type of Product (T, FI, MP, EP)	99.2 % T(MP)
DP Barcode	D262770
Reviewer	Shyam Mathur, Ph.D

Griffin LLC., has submitted product chemistry data for Fluridone technical(MP) to support its registration.

Table 1: Manufacturing and Impurity Data for the Oxytetracycline dihydrate TGAI/MP.				
GLN	Requirement	MRID	Status <sup>1</sup>	Details and/or Deficiency <sup>2</sup>
830.1550	Product Identity & Disclosure of Ingredients	CSF dated 11-23-99	A	the basic formulation CSF with NC, upper and lower certified limits of AI provided. NC concur with label claim nominal concentration. The registrant reported [REDACTED] impurities which are present at a level of [REDACTED] and therefore, listed in CSF.
830.1600 830.1620 830.1650	Starting Materials & Manufacturing Process	449838-01	A	All the information is provided on the starting materials including name of suppliers, chemical names, CAS numbers, Phy-chem properties, etc. Details are provided on manufacturing process along with chemical equations..
830.1670	Discussion of Impurities	449838-01	A	Discussion of impurities in materials used to produce the product, side reaction products and impurities due to post-production reactions or degradation are provided.
830.1700	Preliminary Analysis	449838-03 449838-04	A	Five batches of the technical were analyzed by GLC method No. TM-1235 and GC-MS method No. TM-1243. Both methods are validated for precision, accuracy, & linearity.
830.1750	Certification of Limits	CSF dated 11-23-99	A	NC, UCL & LCL of the AI and NC and UCL of the impurities are provided as per 40CFR158.175b2.
830.1800	Analytical Methods	449838-04	A	The GC-MS method was used for determination of the AI and all other [REDACTED] impurities.
<sup>1</sup> A = Acceptable; N = Unacceptable (see Deficiency); N/A = Not Applicable. <sup>2</sup> Refer to CBI Appendix A for details.				

ATTACHMENT: CONFIDENTIAL APPENDIX





Table 2: Physical and Chemical Properties for the				
GLN	Requirement	MRID	Status <sup>1</sup>	Result <sup>2</sup> or Deficiency
830.6302	Color	449838-05	A	White
830.6303	Physical State	449838-05	A	Solid
830.6304	Odor	" "	NA	
830.6313	Stability	" "	NA	
830.6314	Oxidation/Reduction	" "	A	Did not show any oxidizing or reducing property
830.6315	Flammability		NA	
830.6316	Explosibility		NA	
830.6317	Storage Stability	" "	NA	PR 92-5.
830.6319	Miscibility		NA	
830.6320	Corrosion Characteristics	" "	U	2 weeks test did not show any corrosive activity. 1 Year Test is required.
830.7000	pH	" "	A	7.1
830.7050	UV/Visible Absorption		NA	
830.7100	Viscosity		N/A	The T is a solid at room temperature.
830.7200	Melting Point/ Melting Range	" "	A	147.7° C
830.7220	Boiling Point/ Boiling Range		N/A	TGAI is a solid at room temperature.
830.7300	Density/ Relative Density/ Bulk Density	" "	A	0.38 g/cc
830.7370	Dissociation Constant in Water	" "	NA	
830.7550 830.7560 830.7570	Partition Coefficient (Octanol/Water)	" "	NA	
830.7840 830.7860	Solubility	" "	NA	
830.7950	Vapor Pressure	" "	NA	
<sup>1</sup> A = Acceptable; N = Unacceptable (see Deficiency); N/A = Not applicable. <sup>2</sup> For example, "brown" for 830.6302; "155° C" for 830.7200.				





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES  
AND  
TOXIC SUBSTANCES

TECHNICAL REVIEW BRANCH  
SIMILARITY CLINIC DETERMINATION

03/MAR/2000

Subject: EPA Reg. No./File Symbol: 1812-UGA      Technical Fluridone  
DP Barcode: D262771  
Case No: 065180  
PC Code: 112900

From: Eugenia McAndrew, Biologist *Em*  
Technical Review Branch *Scr*  
Registration Division (7505 C)

To: Daniel Kenny, PM Team 23  
Herbicide Branch  
Registration Division (7505 C)

Applicant: Griffin L.L.C.  
P.O. Box 1847  
Valdosta, Georgia 31603-1847

**ACTION REQUESTED:** TRB has been asked to determine if File Symbol No. 1812-UGA, Technical Fluridone, is substantially similar to EPA Reg. No. 67690-6, Sonar Technical.

**RECOMMENDATIONS:** We have evaluated the formulations of File Symbol No. 1812-UGA and EPA Reg. No. 67690-6 and have found them to be substantially similar. The new product should have the same precautionary and first aid statements as the cited product.

This memorandum pertains only to the decision concerning whether the subject product is similar to the cited product from an acute toxicological view point. For the purposes of this action, TRB has made no determination of the adequacy of the toxicological data base or the precautionary label of the cited product.





449838-00

December 3, 1999

Ms. Joanne I. Miller (23)  
Document Processing Desk (APPL)  
Registration Division (H7505C)  
U.S. Environmental Protection Agency  
Room 266A, Crystal Mall No. 2  
1921 Jefferson Davis Highway  
Arlington, Virginia 22202

Dear Ms. Miller:

**SUBJECT: APPLICATION FOR "ME-TOO" PESTICIDE REGISTRATION  
REQUEST EXPEDITED REVIEW  
TECHNICAL FLURIDONE (EPA REG. NO. 1812-\_\_\_\_\_)  
CITE-ALL METHOD OF SUPPORT**

The undersigned, GRIFFIN L.L.C., does hereby make application for a "Me-Too" pesticide registration for Technical Fluridone, a manufacturing use product containing 99.2% fluridone (1-methyl-3-phenyl-5-[3-(trifluoromethyl)phenyl]-4(1H)-pyridinone). This product is also referred to as GX-648 in Griffin research studies. Technical Fluridone is substantially similar to Sonar Technical (EPA Reg. No. 67690-6), a currently registered product of SePRO Corporation. Griffin is using the cite-all method of support for this registration.

Enclosed in the Administrative Materials are: one (1) Application for Pesticide Registration, five (5) copies of proposed labeling, one (1) Confidential Statement of Formula, one (1) Certification with Respect to Citation of Data (with Data Matrix), and one letter offering to pay data compensation.

Also submitted herewith to satisfy the respective guideline requirements are three separately bound copies of each of the following documents:

<u>Guideline Number</u>	<u>Document Number</u>	<u>Name of Study</u>
830.1550 - 830.1670	P99-025	Griffin Technical Fluridone - Product Identity and Composition 44983801

Griffin L.L.C.

P.O. Box 1847 • Valdosta, GA 31603-1847  
2509 Rocky Ford Rd. • Valdosta, GA 31601  
Telephone: (912) 242-8635  
Facsimile: 912-244-5813



December 3, 1999  
Page 2

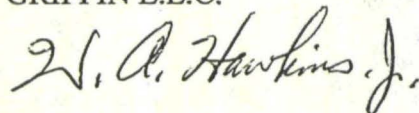
<u>Guideline Number</u>	<u>Document Number</u>	<u>Name of Study</u>
830.1700 - 830.1750	P99-025	Griffin Technical Fluridone - Analysis and Certification of Product Ingredients 44983802
830.1800	TM-1235	Griffin Analytical Method TM-1235: Fluridone in Technical and Formulated Product by GLC 44983803
830.1800	TM-1243	Griffin Analytical Method TM-1243: Fluridone Impurities by GC/MS 44983804
830.6302 - 830.7950	P99-025	Technical Fluridone - Physical and Chemical Properties 44983805

We trust that the Agency will find this application to register Technical Fluridone to be complete and acceptable.

Should you require any additional information, please contact me at 912-293-4242, Extension 1104.

Sincerely,

GRIFFIN L.L.C.



W. A. Hawkins, Jr., Ph.D.  
Registration Manager, Copper Products  
and State Affairs

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U.S. ENVIRONMENTAL PROTECTION AGENCY  
Office of Pesticide Programs

GRIFFIN CORP  
P.O. BOX 1847  
VALDOSTA, GA 316031847

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your transmittal of 12/06/99. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.



NIFT  
Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060



United States  
Environmental Protection Agency  
Washington, DC 20460

☒ Registration  
☐ Amendment  
☐ Other

OPP Identifier Number  
**266704**

### Application for Pesticide - Section I

1. Company/Product Number <b>1812-UGA</b>	2. EPA Product Manager <b>Joanne I. Miller</b>	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) <b>Technical Fluridone</b>	PM# <b>23</b>	
5. Name and Address of Applicant (Include ZIP Code) <b>Griffin L.L.C. P.O. Box 1847 Valdosta, GA 31603-1847</b> <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: <b>EPA Reg. No. 67690-6</b>  Product Name <b>Sonar Technical</b>	

### Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input checked="" type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

### Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	
<input checked="" type="checkbox"/> Certification must be submitted	If "Yes" Unit Packaging wgt. _____ No. per container _____	If "Yes" Package wgt. _____ No. per container _____		<input type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input checked="" type="checkbox"/> Other (Specify) <b>Fiber drum</b>	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container <b>30 gallon, 55 gallon</b>		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled <input type="checkbox"/> Other _____					

### Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name <b>W.A. Hawkins, Jr.</b>	Title <b>Registration Manager</b>	Telephone No. (Include Area Code) <b>912-293-4242 ext. 1104</b>	
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment both under applicable law.		<b>6. Date Application Received (Stamped)</b> 	
2. Signature 	3. Title <b>Registration Manager</b>		
4. Typed Name <b>W.A. Hawkins, Jr.</b>	5. Date <b>12/3/99</b>		

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## PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

**PAPERWORK REDUCTION ACT NOTICE:** Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, (2136), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460.

**INSTRUCTIONS:** This form is to be used for all applications for new registration, end use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Matrices where applicable.

**Submission of Labeling** - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission or a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

**Submission of Data** - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

**SPECIFIC INSTRUCTIONS:** Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

**Block A** - Check the appropriate action for which you are submitting this form.

**SECTION I** - This section must be completed, as applicable, for all registration actions.

1. **Company/Product Number** - Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. **EPA Product Manager** - If known, fill in the name and PM number of the EPA Product Manager.
3. **Proposed Classification** - Specify the proposed classification of this product.
4. **Product Name** - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. **Name and Address of Applicant** - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. **Expedited Review** - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

**SECTION II** - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. **Subject of submission** - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; "general label revision of use directions." Attach a separate page if additional space is needed.

**SECTION III** (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. **Type of Packaging** - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. **Type of Retail Container** - Indicate type of container in which product will be marketed.
3. **Location of Net Contents** - Indicate the location of the net contents information for your product.
4. **Size(s) of Retail Container** - Specify the net contents of all retail containers for your product.
5. **Location of Use Directions** - Indicate the location of the use directions for your product.
6. **Manner in which label is affixed to product** - Indicate the method product label is attached to retail container.

**SECTION IV** (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

- 1-5. Self-explanatory.
6. EPA Use Only.





**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
**401 M Street, S.W.**  
**WASHINGTON, D.C. 20460**

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the completed form to this address.

**Certification with Respect to Citation of Data**

Applicant's/Registrant's Name, Address, and Telephone Number Griffin L.L.C. P.O. Box 1847 Valdosta, GA 31603-1847	EPA Registration Number/File Symbol 1812- <del>46A</del> 436
Active Ingredient(s) and/or representative test compound(s) Fluridone (CAS#59756-60-4)	Date 12/3/99
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Aquatic Food Crop, Aquatic Noncrop	Product Name Technical Fluridone

**NOTE:** If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☒ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

**SECTION I: METHOD OF DATA SUPPORT (Check one method only)**



I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).



I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

**SECTION II: GENERAL OFFER TO PAY**

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]



I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

**SECTION III: CERTIFICATION**

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature <i>W.A. Hawkins, Jr.</i>	Date 12/3/99	Typed or Printed Name and Title W.A. Hawkins, Jr. Registration Manager
---------------------------------------	-----------------	--





VIA CERTIFIED MAIL

December 3, 1999

Registration Manager  
Dow AgroSciences  
9330 Zionsville Road  
Indianapolis, Indiana 46268-1054

To Whom It May Concern:

Griffin L.L.C., 2509 Rocky Ford Road, Valdosta, Georgia 31601 intends to apply for registration for a technical grade active ingredient, Technical Fluridone, containing fluridone as the active ingredient. We will support our registration application by use of the "cite-all" method of data citation as more fully described in 40 CFR Sections 152.86 and 152.93. DowElanco is listed on the current "Listing of Pesticide Data Submitters" at EPA as a company that has submitted data to support registration of fluridone.

We hereby offer to pay compensation to the extent required by FIFRA Section 3(c)(1)(F) for each pertinent compensable study and offer to commence negotiations to determine the amount and terms of compensation, if any, to be paid.

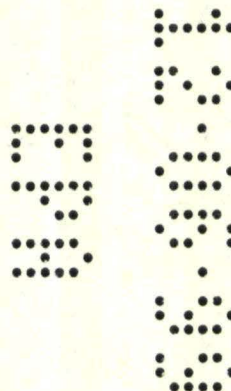
Please identify within 60 days of receipt of this notice the pertinent studies for which you believe compensation is due.

Should you require any additional information, please contact me at 912-293-4242, Extension 1104.

Sincerely,

GRIFFIN L.L.C.

W. A. Hawkins, Jr., Ph.D.  
Registration Manager, Copper Products  
and State Affairs



Griffin L.L.C.

P.O. Box 1847 • Valdosta, GA 31603-1847  
2509 Rocky Ford Rd. • Valdosta, GA 31601  
Telephone: (912) 242-8635  
Facsimile: 912-244-5813





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street, S.W.  
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

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### DATA MATRIX

Date December 3, 1999		EPA Reg No./File Symbol 1812-UGA		Page 1 of 1	
Applicant's/Registrant's Name & Address Griffin L.L.C. P.O. Box 1847 Valdosta, GA 31603-1847		Product Technical Fluridone			
Ingredient Fluridone (CAS#59756-60-4)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
CITE-ALL			Dow Elanco	PAY	
Signature W.A. Hawkins, Jr.	Name and Title W.A. Hawkins, Jr. Registration Manager		Date 12/3/99		

**ADMINISTRATIVE MATERIALS**

**APPLICATION TO REGISTER A NEW PESTICIDE PRODUCT**

**TECHNICAL FLURIDONE**

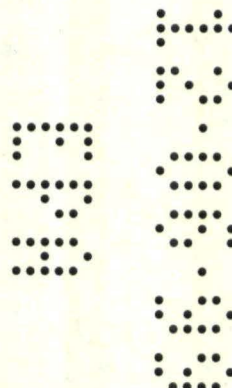
**EPA REG. NO. 1812-LGA**

**DATE SUBMITTED**

DECEMBER 3, 1999

**SUBMITTED BY**

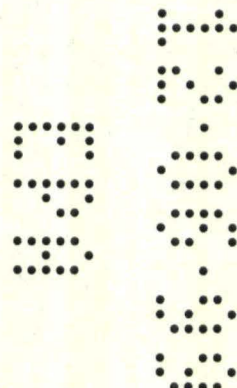
GRIFFIN L.L.C.  
P.O. BOX 1847  
VALDOSTA, GEORGIA 31603-1847





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**FOR ADMINISTRATIVE MATERIALS**

	<u>Page</u>
Application for "Me-Too" Pesticide Registration	Not Paginated
Proposed Labeling for Technical Fluridone (5 Copies)	Not Paginated
Confidential Statement of Formula for Technical Fluridone	Not Paginated
Certification with Respect to Citation of Data (with Data Matrix)	Not Paginated
Offer to Pay Data Compensation	Not Paginated



**GRIFFIN L.L.C.**  
**DECEMBER 3, 1999**

**CONTENTS OF SUBMISSION**

**"Me-Too" Application to Register Technical Fluridone**

A. Administrative Materials

B. Three copies each of the following:

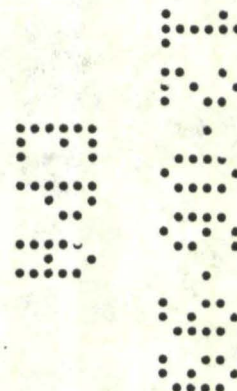
1. Transmittal Document
2. Griffin Technical Fluridone – Product Identity and Composition
3. Griffin Technical Fluridone – Analysis and Certification of Product Ingredients
4. Griffin Analytical Method TM-1235: Fluridone in Technical and Formulated Product by GLC
5. Griffin Analytical Method TM-1243: Fluridone Impurities by GC/MS
6. Technical Fluridone – Physical and Chemical Properties

**"Me-Too" Application to Register the End-Use Aquatic Herbicide Fluridone SC**

A. Administrative Materials

B. Three copies each of the following:

1. Transmittal Document
2. Fluridone SC Product Chemistry Data







UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

12/06/99

OFFICE OF  
PREVENTION, PESTICIDE AND  
TOXIC SUBSTANCES

Griffin L.L. C.  
P.O. Box 1847  
Valdosta, GA 31603-1847

PRODUCT NAME: Technical Fluridone  
COMPANY NAME: Griffin L.L.C.  
OPP IDENTIFICATION NUMBER: 266704  
EPA FILE SYMBOL: 1812-UGA  
EPA RECEIPT DATE: 12/06/99

SUBJECT: RECEIPT OF APPLICATION FOR A NEW REGISTRATION

DEAR REGISTRANT:

The Office of Pesticides Programs has received your application for a new registration and it has passed an administrative screen for completeness.

Please note that this is only a notification of receipt of your application. This is only the first step in the application process, and does NOT constitute approval.

If you have any questions please contact Joanne I. Miller, Product Manager 23 at (703)-305-6224.

Sincerely,

A handwritten signature in cursive script, appearing to read "Dawn L. Jones".

Front End Processing Staff  
Information Services Branch  
Information Resources & Services Division

